



KEPUTUSAN MENTERI KESEHATAN REPUBLIK INDONESIA  
NOMOR HK.01.07/MENKES/4745/2021  
TENTANG  
JENIS DAN PENAMAAN ALAT KESEHATAN  
DENGAN RAHMAT TUHAN YANG MAHA ESA

MENTERI KESEHATAN REPUBLIK INDONESIA,

- Menimbang : a. bahwa berdasarkan Peraturan Menteri Kesehatan Nomor 62 Tahun 2017 tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik *In Vitro*, dan Perbekalan Kesehatan Rumah Tangga, telah disusun kategori dan sub kategori alat kesehatan;
- b. bahwa untuk memudahkan masyarakat dalam penggunaan alat kesehatan yang diedarkan, perlu dilakukan pembakuan jenis dan penamaan alat kesehatan sesuai kategori dan sub kategori;
- c. bahwa berdasarkan pertimbangan sebagaimana dimaksud dalam huruf a dan huruf b, perlu menetapkan Keputusan Menteri Kesehatan tentang Jenis dan Penamaan Alat Kesehatan;
- Mengingat : 1. Pasal 17 ayat (3) Undang-Undang Dasar Negara Republik Indonesia Tahun 1945;
2. Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 144, Tambahan Lembaran Negara Republik Indonesia Nomor 5063);

3. Peraturan Presiden Nomor 18 Tahun 2021 tentang Kementerian Kesehatan (Lembaran Negara Republik Indonesia Tahun 2021 Nomor 83);
4. Peraturan Menteri Kesehatan Nomor 62 Tahun 2017 tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik *In Vitro* dan Perbekalan Kesehatan Rumah Tangga (Berita Negara Republik Indonesia Tahun 2018 Nomor 82);
5. Peraturan Menteri Kesehatan Nomor 25 Tahun 2020 tentang Organisasi dan Tata Kerja Kementerian Kesehatan (Berita Negara Republik Indonesia Tahun 2020 Nomor 1146);

MEMUTUSKAN:

Menetapkan : KEPUTUSAN MENTERI KESEHATAN TENTANG JENIS DAN PENAMAAN ALAT KESEHATAN.

KESATU : Menetapkan jenis dan penamaan alat kesehatan berdasarkan kategori dan sub kategori alat kesehatan, sebagaimana tercantum dalam Lampiran yang merupakan bagian tidak terpisahkan dari Keputusan Menteri ini.

KEDUA : Penetapan jenis dan penamaan alat kesehatan sebagaimana dimaksud dalam Diktum KESATU merupakan pembakuan untuk jenis, penamaan, dan kelas risiko alat kesehatan berdasarkan kategori dan sub kategori alat kesehatan yang dapat digunakan oleh Fasilitas Pelayanan Kesehatan.

KETIGA : Keputusan Menteri ini mulai berlaku pada tanggal ditetapkan.

Ditetapkan di Jakarta  
pada tanggal 4 Juni 2021


MENTERI KESEHATAN  
REPUBLIK INDONESIA,

ttd.

BUDI G. SADIKIN

Salinan sesuai dengan aslinya  
Kepala Biro Hukum dan Organisasi  
Sekretariat Jenderal Kementerian Kesehatan,



  
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LAMPIRAN  
KEPUTUSAN MENTERI KESEHATAN  
REPUBLIK INDONESIA  
NOMOR HK.01.07/MENKES/4745/2021  
TENTANG  
JENIS DAN PENAMAAN ALAT  
KESEHATAN

01. Peralatan Kimia Klinik dan Toksikologi Klinik

01. Sistem Tes Kimia Klinik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Acid phosphatase (total or prostatic) test system (strip & midstream)	Alat uji asam fosfatase (total atau prostatik) (strip & midstream)	B
002	Acid phosphatase (total or prostatic) test system (card)	Alat uji asam fosfatase (total atau prostatik) (card)	B
003	Acid phosphatase (total or prostatic) test system (kit & cair)	Alat uji asam fosfatase (total atau prostatik) (kit & cair)	B
004	Adrenocorticotrophic hormone (ACTH) test system (strip & midstream)	Alat uji hormon adrenokortikotropik (ACTH) (strip & midstream)	B
005	Adrenocorticotrophic hormone (ACTH) test system (card)	Alat uji hormon adrenokortikotropik (ACTH) (card)	B
006	Adrenocorticotrophic hormone (ACTH) test system (kit & cair)	Alat uji hormon adrenokortikotropik (ACTH) (kit & cair)	B
007	Albumin test system (strip & midstream)	Alat uji albumin (strip & midstream)	B
008	Albumin test system (card)	Alat uji albumin (card)	B
009	Albumin test system (kit & cair)	Alat uji albumin (kit & cair)	B
010	Aldosterone test system (strip & midstream)	Alat uji aldosteron (strip & midstream)	B
011	Aldosterone test system (card)	Alat uji aldosteron (card)	B
012	Aldosterone test system (kit & cair)	Alat uji aldosteron (kit & cair)	B

013	Alkaline phosphatase or isoenzymes test system (strip & midstream)	Alat uji alkalin fosfatase (ALP) atau isoenzim (strip & midstream)	B
014	Alkaline phosphatase or isoenzymes test system (card)	Alat uji alkalin fosfatase (ALP) atau isoenzim (card)	B
015	Alkaline phosphatase or isoenzymes test system (kit & cair)	Alat uji alkalin fosfatase (ALP) atau isoenzim (kit & cair)	B
016	Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry (strip & midstream)	Alat uji asam amino, karnitin bebas, dan asilkarnitin untuk uji penapisan pada bayi baru lahir menggunakan spektrometer tandem massa (strip & midstream)	B
017	Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry (card)	Alat uji asam amino, karnitin bebas, dan asilkarnitin untuk uji penapisan pada bayi baru lahir menggunakan spektrometer tandem massa (card)	B
018	Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry (kit & cair)	Alat uji asam amino, karnitin bebas, dan asilkarnitin untuk uji penapisan pada bayi baru lahir menggunakan spektrometer tandem massa (kit&cair)	B
019	Delta-aminolevulinic acid test system (strip & midstream)	Alat uji asam delta-aminolevulinat (strip&midstream)	A
020	Delta-aminolevulinic acid test system (card)	Alat uji asam delta-aminolevulinat (card)	A
021	Delta-aminolevulinic acid test system (kit & cair)	Alat uji asam delta-aminolevulinat (kit & cair)	A
022	Amylase test system (strip & midstream)	Alat uji amilase (strip & midstream)	B
023	Amylase test system (card)	Alat uji amilase (card)	B
024	Amylase test system (kit & cair)	Alat uji amilase (kit & cair)	B
025	Angiotensin I and renin test system (strip & midstream)	Alat uji angiotensin I dan renin (strip&midstream)	B

026	Angiotensin I and renin test system (card)	Alat uji angiotensin I dan renin (card)	B
027	Angiotensin I and renin test system (kit & cair)	Alat uji angiotensin I dan renin (kit&cair)	B
028	Angiotensin converting enzyme (A.C.E.) test system (strip & midstream)	Alat uji angiotensin <i>converting enzyme</i> (A.C.E.) (strip & midstream)	B
029	Angiotensin converting enzyme (A.C.E.) test system (card)	Alat uji angiotensin <i>converting enzyme</i> (A.C.E.) (card)	B
030	Angiotensin converting enzyme (A.C.E.) test system (kit & cair)	Alat uji angiotensin <i>converting enzyme</i> (A.C.E.) (kit&cair)	B
031	Aspartate amino transferase (AST/SGOT) test system (strip & midstream)	Alat uji aspartat amino transferase (AST/SGOT) (strip & midstream)	B
032	Aspartate amino transferase (AST/SGOT) test system (card)	Alat uji aspartat amino transferase (AST/SGOT) (card)	B
033	Aspartate amino transferase (AST/SGOT) test system (kit & cair)	Alat uji aspartat amino transferase (AST/SGOT) (kit & cair)	B
034	Bilirubin (total or direct) test system (strip & midstream)	Alat uji bilirubin (total atau terkonjugasi) (strip & midstream)	B
035	Bilirubin (total or direct) test system (card)	Alat uji bilirubin (total atau terkonjugasi) (card)	B
036	Bilirubin (total or direct) test system (kit & cair)	Alat uji bilirubin (total atau terkonjugasi) (kit & cair)	B
037	Bilirubin (total and unbound) in the neonate test system (strip & midstream)	Alat uji bilirubin (total & <i>unbound</i> ) pada neonatus (strip & midstream)	B
038	Bilirubin (total and unbound) in the neonate test system (card)	Alat uji bilirubin (total & <i>unbound</i> ) pada neonatus (strip & midstream) (card)	B
039	Bilirubin (total and unbound) in the neonate test system (kit & cair)	Alat uji bilirubin (total & <i>unbound</i> ) pada neonatus (strip & midstream) (kit & cair)	B
040	B-type natriuretic peptide test	Alat uji <i>B-type natriuretic</i>	C

	system (strip & midstream)	<i>peptide</i> /BNP (strip & midstream)	
041	B-type natriuretic peptide test system (card)	Alat uji <i>B-type natriuretic peptide</i> /BNP (card)	C
042	B-type natriuretic peptide test system (kit & cair)	Alat uji <i>B-type natriuretic peptide</i> /BNP (kit & cair)	C
043	Biotinidase test system (strip & midstream)	Alat uji biotinidase (strip & midstream)	B
044	Biotinidase test system (card)	Alat uji biotinidase (card)	B
045	Biotinidase test system (kit & cair)	Alat uji biotinidase (kit & cair)	B
046	Blood gases (P CO <sub>2</sub> , P O <sub>2</sub> ) and blood pH test system (strip & midstream)	Alat uji gas darah (P CO <sub>2</sub> , P O <sub>2</sub> ) dan pH darah (strip & midstream)	B
047	Blood gases (P CO <sub>2</sub> , P O <sub>2</sub> ) and blood pH test system (card)	Alat uji gas darah (P CO <sub>2</sub> , P O <sub>2</sub> ) dan pH darah (card)	B
048	Blood gases (P CO <sub>2</sub> , P O <sub>2</sub> ) and blood pH test system (kit & cair)	Alat uji gas darah (P CO <sub>2</sub> , P O <sub>2</sub> ) dan pH darah (kit & cair)	B
049	Calcitonin test system (strip & midstream)	Alat uji kalsitonin (strip & midstream)	B
050	Calcitonin test system (card)	Alat uji kalsitonin (card)	B
051	Calcitonin test system (kit & cair)	Alat uji kalsitonin (kit & cair)	B
052	Calcium test system (strip & midstream)	Alat uji kalsium (strip & midstream)	B
053	Calcium test system (card)	Alat uji kalsium (card)	B
054	Calcium test system (kit & cair)	Alat uji kalsium (kit & cair)	B
055	Calibrator (strip)	Kalibrator (strip)	B
056	Calibrator (cair)	Kalibrator (cair)	B
057	Human chorionic gonadotropin (HCG) test system (strip & midstream)	Alat uji kehamilan/HCG (strip & midstream)	B
058	Human chorionic gonadotropin (HCG) test system (card)	Alat uji kehamilan/HCG (card)	B
059	Human chorionic gonadotropin (HCG) test system (kit & cair)	Alat uji kehamilan/HCG (kit & cair)	B

060	Bicarbonate/carbon dioxide test system (strip & midstream)	Alat uji bikarbonat/karbondioksida (strip & midstream)	B
061	Bicarbonate/carbon dioxide test system (card)	Alat uji bikarbonat/karbondioksida (card)	B
062	Bicarbonate/carbon dioxide test system (kit & cair)	Alat uji bikarbonat/karbondioksida (kit & cair)	B
063	Chloride test system (strip & midstream)	Alat uji klorida (strip & midstream)	B
064	Chloride test system (card)	Alat uji klorida (card)	B
065	Chloride test system (kit & cair)	Alat uji klorida (kit & cair)	B
066	Cholyglycine test system (strip & midstream)	Alat uji <i>cholyglycine</i> (CG) (strip & midstream)	B
067	Cholyglycine test system (card)	Alat uji <i>cholyglycine</i> (CG) (card)	B
068	Cholyglycine test system (kit & cair)	Alat uji <i>cholyglycine</i> (CG) (kit & cair)	B
069	Conjugated sulfolithocholic acid (SLCG) test system (strip & midstream)	Alat uji asam <i>sulfolithocholic</i> (SLCG) terkonjugasi (strip & midstream)	B
070	Conjugated sulfolithocholic acid (SLCG) test system (card)	Alat uji asam <i>sulfolithocholic</i> (SLCG) terkonjugasi (card)	B
071	Conjugated sulfolithocholic acid (SLCG) test system (kit & cair)	Alat uji asam <i>sulfolithocholic</i> (SLCG) terkonjugasi (kit & cair)	B
072	Cortisol (hydrocortisone and hydroxycorticosterone) test system (strip & midstream)	Alat uji kortisol (hidrokortison dan hidrosikortikosteron) (strip & midstream)	B
073	Cortisol (hydrocortisone and hydroxycorticosterone) test system (card)	Alat uji kortisol (hidrokortison dan hidrosikortikosteron) (card)	B
074	Cortisol (hydrocortisone and hydroxycorticosterone) test system (kit & cair)	Alat uji kortisol (hidrokortison dan hidrosikortikosteron) (kit & cair)	B
075	Creatine phosphokinase/creatin kinase or isoenzymes test system (strip	Alat uji kreatinin fosfokinase/kreatinin kinase atau isoenzim (strip & midstream)	B



	& midstream)		
076	Creatine phosphokinase/creatine kinase or isoenzymes test system (card)	Alat uji kreatinin fosfokinase/kreatinin kinase atau isoenzim (card)	B
077	Creatine phosphokinase/creatine kinase or isoenzymes test system (kit & cair)	Alat uji kreatinin fosfokinase/kreatinin kinase atau isoenzim (kit & cair)	B
078	Creatinine test system (strip & midstream)	Alat uji kreatinin (strip & midstream)	B
079	Creatinine test system(card)	Alat uji kreatinin (card)	B
080	Creatinine test system (kit & cair)	Alat uji kreatinin (kit & cair)	B
081	Cyclic AMP test system (strip & midstream)	Alat uji <i>cyclic AMP</i> (strip & midstream)	B
082	Cyclic AMP test system (card)	Alat uji <i>cyclic AMP</i> (card)	B
083	Cyclic AMP test system (kit & cair)	Alat uji <i>cyclic AMP</i> (kit & cair)	B
084	Cyclosporine test system(strip & midstream)	Alat uji siklosporin (strip & midstream)	C
085	Cyclosporine test system (card)	Alat uji siklosporin (card)	C
086	Cyclosporine test system (kit & cair)	Alat uji siklosporin (kit & cair)	C
087	Folic acid test system (strip & midstream)	Alat uji asam folat (strip & midstream)	B
088	Galactose-1-phosphate uridyl transferase test system (strip & midstream)	Alat uji galaktosa-1-fosfat uridil transferase (strip & midstream)	B
089	Urinary glucose (nonquantitative) test system (strip & midstream)	Alat uji glukosa pada urin (nonkuantitatif) (strip & midstream)	B
090	Glucose test system (strip & midstream)	Alat uji glukosa/gula darah (strip & midstream)	C
091	Urinary homocystine (nonquantitative) test system	Alat uji homosistein urin (nonkuantitatif) (strip &	B

	(strip & midstream)	midstream)	
092	Hydroxybutyric dehydrogenase test system (strip & midstream)	Alat uji hidroksibutirat dehidrogenase (strip & midstream)	A
093	Lactate dehydrogenase test system (strip & midstream)	Alat uji laktat dehidrogenase/LADH (strip & midstream)	B
094	Lactate dehydrogenase isoenzymes test system (strip & midstream)	Alat uji isoenzim laktat dehidrogenase/LADH (strip & midstream)	B
095	Lecithin/sphingomyelin ratio in amniotic fluid test system (strip & midstream)	Alat uji rasio lesitin/sphingomyelin pada cairan amniotik (strip & midstream)	B
096	Methylmalonic acid (nonquantitative) test system (strip & midstream)	Alat uji asam metilmalonat (strip & midstream)	B
097	5'-Nucleotidase test system (strip & midstream)	Alat uji 5'-nukleotidase (strip & midstream)	A
098	Parathyroid hormone test system (strip & midstream)	Alat uji hormon paratiroid (strip & midstream)	B
099	Phenylalanine test system (strip & midstream)	Alat uji fenilalanina (strip & midstream)	B
100	Human placental lactogen test system (strip & midstream)	Alat uji human placental lactogen (HPL) (strip & midstream)	B
101	Potassium test system (strip & midstream)	Alat uji kalium (strip & midstream)	B
102	Total protein test system (strip & midstream)	Alat uji total protein (strip & midstream)	B
103	Sodium test system (strip & midstream)	Alat uji natrium (strip & midstream)	B
104	Tacrolimus test system (strip & midstream)	Alat uji tacrolimus (strip & midstream)	C
105	Thyroxine-binding globulin test system (strip & midstream)	Alat uji <i>thyroxine-binding globulin</i> (TBG) (strip & midstream)	B
106	Thyroid stimulating hormone	Alat uji <i>thyroid stimulating</i>	B

	test system (strip & midstream)	<i>hormone</i> (TSH) (strip & midstream)	
107	Free thyroxine test system (strip & midstream)	Alat uji tiroksin / T4 bebas (strip & midstream)	B
108	Total thyroxine test system (strip & midstream)	Alat uji tiroksin total / T4 (strip & midstream)	B
109	Total triiodothyronine test system (strip & midstream)	Alat uji triiodotironina total / T3 (strip & midstream)	B
110	Triiodothyronine uptake test system (strip & midstream)	Alat uji triiodotironina / T3 uptake (T3-uptake) (strip & midstream)	B
111	Urea nitrogen test system (strip & midstream)	Alat uji urea nitrogen / BUN (strip & midstream)	B
112	Vitamin B12 test system (strip & midstream)	Alat uji vitamin B12/sianokobalamin (strip & midstream)	B
113	Vitamin D test system (strip & midstream)	Alat uji vitamin D, ergokalsiferol (strip & midstream)	B
114	Folic acid test system (card)	Alat uji asam folat (card)	B
115	Galactose-1-phosphate uridyl transferase test system (card)	Alat uji galaktosa-1-fosfat uridil transferase (card)	B
116	Urinary glucose (nonquantitative) test system (card)	Alat uji glukosa pada urin (nonkuantitatif) (card)	B
117	Glucose test system (card)	Alat uji glukosa/gula darah (card)	C
118	Urinary homocystine (nonquantitative) test system (card)	Alat uji homosistein urin (nonkuantitatif) (card)	B
119	Hydroxybutyric dehydrogenase test system (card)	Alat uji hidroksibutirat dehidrogenase (card)	A
120	Lactate dehydrogenase test system (card)	Alat uji laktat dehidrogenase/LADH (card)	B
121	Lactate dehydrogenase isoenzymes test system (card)	Alat uji isoenzim laktat dehidrogenase/LADH (card)	B
122	Lecithin/sphingomyelin ratio in amniotic fluid test system (card)	Alat uji rasio lesitin/sphingomyelin pada	B

		cairan amniotik (card)	
123	Methylmalonic acid (nonquantitative) test system (card)	Alat uji asam metilmalonat (card)	B
124	5'-Nucleotidase test system (card)	Alat uji 5'-nukleotidase (card)	A
125	Parathyroid hormone test system (card)	Alat uji hormon paratiroid (card)	B
126	Phenylalanine test system (card)	Alat uji fenilalanina (card)	B
127	Human placental lactogen test system (card)	Alat uji human placental lactogen (HPL) (card)	B
128	Potassium test system (card)	Alat uji kalium (card)	B
129	Total protein test system (card)	Alat uji protein total (card)	B
130	Sodium test system (card)	Alat uji natrium (card)	B
131	Tacrolimus test system (card)	Alat uji tacrolimus (card)	C
132	Thyroxine-binding globulin test system (card)	Alat uji <i>thyroxine-binding globulin</i> (TBG) (card)	B
133	Thyroid stimulating hormone test system (card)	Alat uji <i>thyroid stimulating hormone</i> hormon (TSH) (card)	B
134	Free thyroxine test system (card)	Alat uji tiroksin /T4 bebas (card)	B
135	Total thyroxine test system (card)	Alat uji tiroksin total /T4 (card)	B
136	Total triiodothyronine test system (card)	Alat uji triiodotironina total/ T3 (card)	B
137	Triiodothyronine uptake test system (card)	Alat uji triiodotironina / T3 <i>uptake</i> (card)	B
138	Urea nitrogen test system (card)	Alat uji urea nitrogen / BUN (card)	B
139	Vitamin B12 test system (card)	Alat uji vitamin B12/sianokobalamin (card)	B
140	Vitamin D test system (card)	Alat uji vitamin D, ergokalsiferol (card)	B
141	Folic acid test system (kit & cair)	Alat uji asam folat (kit & cair)	B

142	Galactose-1-phosphate uridyl transferase test system (kit & cair)	Alat uji galaktosa-1-fosfat uridil transferase (kit&cair)	B
143	Urinary glucose (nonquantitative) test system (kit & cair)	Alat uji glukosa pada urin (nonkuantitatif) (kit & cair)	B
144	Glucose test system (kit & cair)	Alat uji glukosa/ gula darah (kit & cair)	C
145	Urinary homocystine (nonquantitative) test system (kit & cair)	Alat uji homosistein urin (nonkuantitatif) (kit&cair)	B
146	Hydroxybutyric dehydrogenase test system (kit & cair)	Alat uji hidrosibutirat dehidrogenase (kit&cair)	A
147	Ketones (nonquantitative) test system (kit & cair)	Alat uji keton (nonkuantitatif) (kit & cair)	B
148	Lactate dehydrogenase test system (kit & cair)	Alat uji laktat dehidrogenase/LADH (kit & cair)	B
149	Lactate dehydrogenase isoenzymes test system (kit & cair)	Alat uji isoenzim laktat dehidrogenase/LADH (kit & cair)	B
150	Lecithin/sphingomyelin ratio in amniotic fluid test system (kit & cair)	Alat uji rasio lesitin/sphingomyelin pada cairan amniotik (kit&cair)	B
151	Methylmalonic acid (nonquantitative) test system (kit & cair)	Alat uji asam metilmalonat (kit & cair)	B
152	5'-Nucleotidase test system (kit & cair)	Alat uji 5'-nukleotidase (kit&cair)	A
153	Parathyroid hormone test system (kit & cair)	Alat uji hormon paratiroid (kit & cair)	B
154	Phenylalanine test system (kit & cair)	Alat uji fenilalanina (kit & cair)	B
155	Human placental lactogen test system (kit & cair)	Alat uji human placental lactogen (HPL) (kit & cair)	B
156	Potassium test system (kit & cair)	Alat uji kalium (kit & cair)	B

157	Total protein test system (kit & cair)	Alat uji total protein (kit & cair)	B
158	Sodium test system (kit & cair)	Alat uji natrium (kit & cair)	B
159	Tacrolimus test system (kit & cair)	Alat uji tacrolimus (kit & cair)	C
160	Thyroxine-binding globulin test system (kit & cair)	Alat uji <i>thyroxine-binding globulin</i> (TBG) (kit & cair)	B
161	Thyroid stimulating hormone test system (kit & cair)	Alat uji <i>thyroid stimulating hormone</i> (TSH) (kit & cair)	B
162	Free thyroxine test system (kit & cair)	Alat uji tiroksin / T4 bebas (kit & cair)	B
163	Total thyroxine test system (kit & cair)	Alat uji total tiroksin / T4 (kit & cair)	B
164	Total triiodothyronine test system (kit & cair)	Alat uji total triiodotironina / T3 (kit & cair)	B
165	Triiodothyronine uptake test system (kit & cair)	Alat uji triiodotironina / T3 <i>uptake</i> (kit & cair)	B
166	Triose phosphate isomerase test system (kit & cair)	Alat uji triomer fosfat isomerase (kit & cair)	B
167	Urea nitrogen test system (kit & cair)	Alat uji urea nitrogen /BUN (kit & cair)	B
168	Vitamin A test system (kit & cair)	Alat uji vitamin A (kit & cair)	B
169	Vitamin B12 test system (kit & cair)	Alat uji vitamin B12/sianokobalamin (kit & cair)	B
170	Vitamin D test system (kit & cair)	Alat uji vitamin D, ergokalsiferol (kit & cair)	B
171	Multi parameter clinical chemistry test system	Alat uji kimia Klinis Multiparameter	C
172	Bilirubin (total and unbound) in the neonate test system	Alat uji Blirubin total dan unbound pada Neonatus	B
173	Blood specimen collection device	Alat pengumpul sampel darah	B
174	Neutrophil gelatinase associated lipocalin	Alat uji NGAL	C
175	Human chorionic gonadotropin (HCG) test system	Alat uji kehamilan	B

176	Glucose test system	Alat uji glukosa/gula darah	C
177	Vitamin B12 test system	Alat uji vitamin B12/sianokobalamin	B
178	Blood gases (P CO <sub>2</sub> , P O <sub>2</sub> ) and blood pH test system	Alat uji gas darah (P CO <sub>2</sub> , P O <sub>2</sub> ) dan pH darah	B
179	Total protein test system	Alat uji protein total	B
180	Bilirubin (total or direct) test system	Alat uji bilirubin (total atau terkonjugasi)	C
181	B-type natriuretic peptide test system	Alat uji <i>B-type natriuretic peptide</i> /BNP	B
182	Sodium test system	Alat uji Natrium	B
183	Anti-Mullerian Hormone Test System (card)	Alat uji hormon <i>Anti-Mullerian</i> (card)	B
184	Anti-Mullerian Hormone Test System (strip)	Alat uji hormon <i>Anti-Mullerian</i> (strip)	B
185	Anti-Mullerian Hormone Test System (cair)	Alat uji hormon <i>Anti-Mullerian</i> (cair)	B
186	Thyroid stimulating hormone test system	Alat uji <i>thyroid stimulating hormone</i> (TSH)	B
187	5-Fluorouracil Test System	Alat uji 5-Fluorouracil	B
188	Artificial Pancreas Device Test System	Alat uji pankreas buatan	C
189	Artificial Pancreas Device Test System, Bihormonal Control	Alat uji pankreas buatan, kontrol bihormonal	C
190	Artificial Pancreas Device Test System, Single Hormonal Control	Alat uji pankreas buatan, kontrol <i>single</i> hormonal	C
191	Fetal Fibronectin Test System	Alat uji fibronektin janin	C
192	Hyaline Membrane Disease Assay	Alat uji membran hialin	C
193	Total Antioxidant test system	Alat uji total antioksidan	C
194	Volatile Organic Compounds Breath Analysis Test system	Alat uji analisis senyawa organik <i>volatile</i> pada nafas	C
195	Alanine amino transferase (ALT/SGPT) test system (strip & midstream)	Alat uji <i>alanine aminotransferase</i> (ALT / SGPT)/ alat uji fungsi hati (strip & midstream)	B

196	Alanine amino transferase (ALT/SGPT) test system (card)	Alat uji <i>alanine aminotransferase</i> (ALT / SGPT)/ alat uji fungsi hati (card)	B
197	Alanine amino transferase (ALT/SGPT) test system (kit & cair)	Alat uji <i>alanine aminotransferase</i> (ALT / SGPT)/ alat uji fungsi hati (kit & cair)	B
198	Aldolase test system (strip & midstream)	Alat uji aldolase (strip & midstream)	B
199	Aldolase test system ( card)	Alat uji aldolase (card)	B
200	Aldolase test system (kit & cair)	Alat uji aldolase (kit & cair)	B
201	Ammonia test system (strip & midstream)	Alat uji amonia (strip & midstream)	B
202	Ammonia test system (card)	Alat uji amonia (card)	B
203	Ammonia test system (kit & cair)	Alat uji amonia (kit & cair)	B
204	Androstenedione test system (strip & midstream)	Alat uji androstenedione (strip & midstream)	B
205	Androstenedione test system (card)	Alat uji androstenedione (card)	B
206	Androstenedione test system (kit & cair)	Alat uji androstenedione (kit & cair)	B
207	Androsterone test system (strip & midstream)	Alat uji androsterone (strip & midstream)	B
208	Androsterone test system (card)	Alat uji androsterone (card)	B
209	Androsterone test system (kit & cair)	Alat uji androsterone (kit & cair)	B
210	Ascorbic acid test system (strip & midstream)	Alat uji asam askorbat/ alat uji vitamin C (strip & midstream)	B
211	Ascorbic acid test system (card)	Alat uji asam askorbat/ alat uji vitamin C (card)	B
212	Ascorbic acid test system (kit & cair)	Alat uji asam askorbat/ alat uji vitamin C (kit & cair)	B
213	Urinary bilirubin and its conjugates (nonquantitative) test system (strip & midstream)	Alat uji bilirubin dan konjugatnya pada urin (nonkuantitatif) (strip & midstream)	B



214	Urinary bilirubin and its conjugates (nonquantitative) test system (card)	Alat uji bilirubin dan konjugatnya pada urin (nonkuantitatif) (card)	B
215	Urinary bilirubin and its conjugates (nonquantitative) test system (kit & cair)	Alat uji bilirubin dan konjugatnya pada urin (nonkuantitatif) (kit & cair)	B
216	Blood volume test system (strip & midstream)	Alat uji volume darah (strip & midstream)	B
217	Blood volume test system (card)	Alat uji volume darah (card)	B
218	Blood volume test system (kit & cair)	Alat uji volume darah (kit & cair)	B
219	C-peptides of proinsulin test system (strip & midstream)	Alat uji C-peptida proinsulin (strip & midstream)	B
220	C-peptides of proinsulin test system (card)	Alat uji C-peptida proinsulin (card)	B
221	C-peptides of proinsulin test system (kit & cair)	Alat uji C-peptida proinsulin (kit & cair)	B
222	Catecholamines (total) test system (strip & midstream)	Alat uji katekolamin (strip & midstream)	B
223	Catecholamines (total) test system (card)	Alat uji katekolamin (card)	B
224	Catecholamines (total) test system (kit & cair)	Alat uji katekolamin (kit & cair)	B
225	Cholesterol (total) test system (strip & midstream)	Alat uji kolesterol (total) (strip & midstream)	B
226	Cholesterol (total) test system (card)	Alat uji kolesterol (total) (card)	B
227	Cholesterol (total) test system (kit & cair)	Alat uji kolesterol (total) (kit & cair)	B
228	Chymotrypsin test system (strip & midstream)	Alat uji <i>chymotrypsin</i> (strip & midstream)	B
229	Chymotrypsin test system (card)	Alat uji <i>chymotrypsin</i> (card)	B
230	Chymotrypsin test system (kit & cair)	Alat uji <i>chymotrypsin</i> (kit & cair)	B
231	Compound S (11-deoxycortisol) test system (strip & midstream)	Alat uji <i>compound S</i> (11-deoxycortisol) (strip & midstream)	B

232	Compound S (11-deoxycortisol) test system (card)	Alat uji <i>compound S</i> (11-deoxycortisol) (card)	B
233	Compound S (11-deoxycortisol) test system (kit & cair)	Alat uji <i>compound S</i> (11-deoxycortisol) (kit & cair)	B
234	Copper test system (strip & midstream)	Alat uji tembaga (strip & midstream)	B
235	Copper test system (card)	Alat uji tembaga (card)	B
236	Copper test system (kit & cair)	Alat uji tembaga (kit & cair)	B
237	Corticoids test system (strip & midstream)	Alat uji kortikoid (strip & midstream)	B
238	Corticoids test system (card)	Alat uji kortikoid (card)	B
239	Corticoids test system (kit & cair)	Alat uji kortikoid (kit & cair)	B
240	Corticosterone test system (strip & midstream)	Alat uji kortikosteron (strip & midstream)	B
241	Corticosterone test system (card)	Alat uji kortikosteron (card)	B
242	Corticosterone test system (kit & cair)	Alat uji kortikosteron (kit & cair)	B
243	Creatine test system (strip & midstream)	Alat uji kreatin (strip & midstream)	B
244	Creatine test system(card)	Alat uji kreatin (card)	B
245	Creatine test system (kit & cair)	Alat uji kreatin (kit & cair)	B
246	Cystine test system(strip & midstream)	Alat uji sistin (strip & midstream)	B
247	Cystine test system (card)	Alat uji sistin (card)	B
248	Cystine test system (kit & cair)	Alat uji sistin (kit & cair)	B
249	Dehydroepiandrosterone (free and sulfate) test system (strip & midstream)	Alat uji <i>dehydroepiandrosterone</i> (bebas dan sulfat) (strip & midstream)	B
250	Dehydroepiandrosterone (free and sulfate) test system (card)	Alat uji <i>dehydroepiandrosterone</i> (bebas dan sulfat) (card)	B
251	Dehydroepiandrosterone (free and sulfate) test system (kit & cair)	Alat uji <i>dehydroepiandrosterone</i> (bebas dan sulfat) (kit & cair)	B
252	Desoxycorticosterone test system (strip & midstream)	Alat uji desoksikortikosteron (strip & midstream)	B

253	Desoxycorticosterone test system(card)	Alat uji desoksikortikosteron (card)	B
254	Desoxycorticosterone test system (kit & cair)	Alat uji desoksikortikosteron (kit & cair)	B
255	2,3-Diphosphoglyceric acid test system(strip & midstream)	Alat uji asam 2,3- <i>diphosphoglyceric</i> (strip & midstream)	B
256	2,3-Diphosphoglyceric acid test system (card)	Alat uji Asam 2,3- <i>diphosphoglyceric</i> (card)	B
257	2,3-Diphosphoglyceric acid test system (kit & cair)	Alat uji Asam 2,3- <i>diphosphoglyceric</i> (kit & cair)	B
258	Estradiol test system(strip & midstream)	Alat uji estradiol (strip & midstream)	B
259	Estradiol test system (card)	Alat uji estradiol (card)	B
260	Estradiol test system (kit & cair)	Alat uji estradiol (kit & cair)	B
261	Estriol test system(strip & midstream)	Alat uji estriol (strip & midstream)	B
262	Estriol test system (card)	Alat uji estriol (card)	B
263	Estriol test system (kit & cair)	Alat uji estriol (kit & cair)	B
264	Estrogens (total, in pregnancy) test system(strip & midstream)	Alat uji estrogen (total, dalam kehamilan) (strip & midstream)	B
265	Estrogens (total, in pregnancy) test system (card)	Alat uji estrogen (total, dalam kehamilan) (card)	B
266	Estrogens (total, in pregnancy) test system (kit & cair)	Alat uji estrogen (total, dalam kehamilan) (kit & cair)	B
267	Estrogens (total, nonpregnancy) test system (strip & midstream)	Alat uji estrogen (total, tidak hamil) (strip & midstream)	B
268	Estrone test system (strip & midstream)	Alat uji estron (strip & midstream)	B
269	Etiocolanolone test system (strip & midstream)	Alat uji <i>etiocolanolone</i> (strip & midstream)	C
270	Fatty acids test system (strip & midstream)	Alat uji asam lemak (strip & midstream)	B
271	Follicle-stimulating hormone test system (strip & midstream)	Alat uji <i>follicle-stimulating hormone</i> (FSH) (strip & midstream)	B

272	Formiminoglutamic acid (FIGLU) test system (strip & midstream)	Alat uji <i>formiminoglutamic acid</i> (FIGLU) (strip & midstream)	B
273	Galactose test system (strip & midstream)	Alat uji galaktosa (strip & midstream)	B
274	Gastric acidity test system (strip & midstream)	Alat uji keasaman lambung (strip & midstream)	B
275	Gastrin test system (strip & midstream)	Alat uji gastrin (strip & midstream)	B
276	Globulin test system (strip & midstream)	Alat uji globulin (strip & midstream)	B
277	Glucagon test system (strip & midstream)	Alat uji glukagon (strip & midstream)	B
278	Gamma-glutamyl transpeptidase and isoenzymes test system (strip & midstream)	Alat uji gamma-glutamil transpeptidase dan isoenzim (strip & midstream)	B
279	Glutathione test system (strip & midstream)	Alat uji glutation (strip & midstream)	B
280	Human growth hormone test system (strip & midstream)	Alat uji <i>human growth hormone</i> (HGH)/ Alat uji hormon pertumbuhan (strip & midstream)	B
281	Histidine test system (strip & midstream)	Alat uji histidin (strip & midstream)	B
282	17-Hydroxycorticosteroids (17-ketogenic steroids) test system (strip & midstream)	Alat uji 17-hidroksikortikosteroid ( <i>17-ketogenic steroids</i> ) (strip & midstream)	B
283	5-Hydroxyindole acetic acid/serotonin test system (strip & midstream)	Alat uji <i>5-hydroxyindoleacetic acid</i> (5-HIAA)/ Alat uji serotonin (strip & midstream)	B
284	17-Hydroxyprogesterone test system (strip & midstream)	Alat uji 17-OH progesteron (17-OHP)/ Alat uji 17-hydroxyprogesterone (strip & midstream)	B
285	Hydroxyproline test system (strip & midstream)	Alat uji hidroksiprolin (strip & midstream)	B
286	Immunoreactive insulin test system (strip & midstream)	Alat uji insulin immunoreaktif (strip & midstream)	B

287	Iron (non-heme) test system (strip & midstream)	Alat uji zat besi (non-heme) (strip & midstream)	B
288	Iron-binding capacity test system (strip & midstream)	Alat uji kapasitas ikat zat besi (strip & midstream)	B
289	Isocitric dehydrogenase test system (strip & midstream)	Alat uji <i>dehidrogenase isocitric</i> (strip & midstream)	B
290	17-Ketosteroids test system (strip & midstream)	Alat uji 17-ketosteroid (strip & midstream)	B
291	Ketones (nonquantitative) test system (strip & midstream)	Alat uji keton (nonkuantitatif) (strip & midstream)	B
292	Lactic acid test system (strip & midstream)	Alat uji asam laktat (strip & midstream)	B
293	Leucine aminopeptidase test system (strip & midstream)	Alat uji leusin aminopeptidase (strip & midstream)	B
294	Lipase test system (strip & midstream)	Alat uji lipase (strip & midstream)	B
295	Lipid (total) test system (strip & midstream)	Alat uji lipid (total) (strip & midstream)	B
296	Lipoprotein test system (strip & midstream)	Alat uji lipoprotein (strip & midstream)	B
297	Luteinizing hormone test system (strip & midstream)	Alat uji <i>luteinizing hormone (LH)</i> / alat uji masa subur/ alat uji ovulasi (strip & midstream)	B
298	Lysozyme (muramidase) test system (strip & midstream)	Alat uji lisozim (muramidase) (strip & midstream)	B
299	Magnesium test system (strip & midstream)	Alat uji magnesium (strip & midstream)	B
300	Malic dehydrogenase test system (strip & midstream)	Alat uji enzim <i>malic dehydrogenase</i> (strip & midstream)	B
301	Mucopolysaccharides (nonquantitative) test system (strip & midstream)	Alat uji <i>mucopolysaccharides</i> (nonkuantitatif) (strip & midstream)	B
302	Nitrite (nonquantitative) test system (strip & midstream)	Alat uji nitrit (nonkuantitatif) (strip & midstream)	B

303	Nitrogen (amino-nitrogen) test system (strip & midstream)	Alat uji nitrogen (amino-nitrogen) (strip & midstream)	B
304	Plasma oncometry test system (strip & midstream)	Alat uji <i>oncometry</i> plasma (strip & midstream)	B
305	Ornithine carbamyl transferase test system (strip & midstream)	Alat uji enzim <i>ornithine carbamyl transferase</i> (OCT) (strip & midstream)	B
306	Osmolality test system (strip & midstream)	Alat uji osmolalitas (strip & midstream)	B
307	Oxalate test system (strip & midstream)	Alat uji oksalat (strip & midstream)	B
308	Urinary pH (nonquantitative) test system (strip & midstream)	Alat uji pH urin (strip & midstream)	B
309	Urinary phenylketones (nonquantitative) test system (strip & midstream)	Alat uji fenilketon urin (strip & midstream)	B
310	6-Phosphogluconate dehydrogenase test system (strip & midstream)	Alat uji <i>6-phosphogluconate dehydrogenase</i> (6PGD) (strip & midstream)	B
311	Phosphohexose isomerase test system (strip & midstream)	Alat uji isomerase fosfoheksosa (strip & midstream)	B
312	Phospholipid test system (strip & midstream)	Alat uji fosfolipid (strip & midstream)	B
313	Phosphorus (inorganic) test system (strip & midstream)	Alat uji fosfor (anorganik) (strip & midstream)	B
314	Porphobilinogen test system (strip & midstream)	Alat uji <i>porphobilinogen</i> (strip & midstream)	B
315	Porphyrins test system (strip & midstream)	Alat uji porfirin (strip & midstream)	B
316	Pregnanediol test system (strip & midstream)	Alat uji pregnanediol (strip & midstream)	B
317	Pregnenolone test system (strip & midstream)	Alat uji <i>pregnenolone</i> (strip & midstream)	B
318	Progesterone test system (strip & midstream)	Alat uji progesteron (strip & midstream)	B

319	Prolactin (lactogen) test system (strip & midstream)	Alat uji prolaktin (laktogen) (strip & midstream)	B
320	Protein (fractionation) test system (strip & midstream)	Alat uji protein (fraksinasi) (strip & midstream)	B
321	Protein-bound iodine test system (strip & midstream)	Alat uji iodin yang terikat dengan protein (strip & midstream)	B
322	Urinary protein or albumin (nonquantitative) test system (strip & midstream)	Alat uji albumin atau protein urin (nonkuantitatif) (strip & midstream)	B
323	Pyruvate kinase test system (strip & midstream)	Alat uji piruvat kinase (strip & midstream)	B
324	Pyruvic acid test system (strip & midstream)	Alat uji asam piruvat (strip & midstream)	B
325	Quality control material (assayed and unassayed) (strip)	Reagen kontrol kualitas ( <i>assayed dan unassayed</i> ) (strip)	B
326	Sorbitol dehydrogenase test system (strip & midstream)	Alat uji sorbitol dehidrogenase (strip & midstream)	B
327	Testosterone test system (strip & midstream)	Alat uji testosteron (strip & midstream)	B
328	Triglyceride test system (strip & midstream)	Alat uji trigliserid (strip & midstream)	B
329	Triose phosphate isomerase test system (strip & midstream)	Alat uji triose fosfat isomerase (strip & midstream)	B
330	Trypsin test system (strip & midstream)	Alat uji tripsin (strip & midstream)	B
331	Free tyrosine test system (strip & midstream)	Alat uji tirosin bebas (strip & midstream)	B
332	Uric acid test system (strip & midstream)	Alat uji asam urat (strip & midstream)	B
333	Urinary calculi (stones) test system (strip & midstream)	Alat uji batu kemih (strip & midstream)	B
334	Urinary urobilinogen (nonquantitative) test system (strip & midstream)	Alat uji urobilinogen urin (nonkuantitatif) (strip & midstream)	B
335	Uroporphyrin test system (strip & midstream)	Alat uji <i>uroporphyrin</i> (strip & midstream)	B

336	Vanilmandelic acid test system (strip & midstream)	Alat uji <i>vanillylmandelic acid</i> (VMA) (strip & midstream)	B
337	Vitamin A test system (strip & midstream)	Alat uji vitamin A (strip & midstream)	B
338	Vitamin E test system (strip & midstream)	Alat uji vitamin E (strip & midstream)	B
339	Xylose test system (strip & midstream)	Alat uji xilosa (strip & midstream)	B
340	Estrogens (total, nonpregnancy) test system (card)	Alat uji estrogen (Total, tidak Hamil) (card)	B
341	Estrone test system (card)	Alat uji estron (card)	B
342	Etiocolanolone test system (card)	Alat uji <i>etiocolanolone</i> (card)	C
343	Fatty acids test system (card)	Alat uji asam lemak (card)	B
344	Follicle-stimulating hormone test system (card)	Alat uji <i>follicle-stimulating hormone</i> (FSH) (card)	B
345	Formiminoglutamic acid (FIGLU) test system (card)	Alat uji <i>formiminoglutamic acid</i> (FIGLU) (card)	B
346	Galactose test system (card)	Alat uji galaktosa (card)	B
347	Gastric acidity test system (card)	Alat uji keasaman lambung (card)	B
348	Gastrin test system (card)	Alat uji gastrin (card)	B
349	Globulin test system (card)	Alat uji globulin (card)	B
350	Glucagon test system (card)	Alat uji glukagon (card)	B
351	Gamma-glutamyl transpeptidase and isoenzymes test system (card)	Alat uji gamma-glutamil transpeptidase dan isoenzim (card)	B
352	Glutathione test system (card)	Alat uji glutation (card)	B
353	Human growth hormone test system (card)	Alat uji human growth hormone (HGH)/ lat uji hormon pertumbuhan (card)	B
354	Histidine test system (card)	Alat uji histidin (card)	B
355	17-Hydroxycorticosteroids (17-ketogenic steroids) test system (card)	Alat uji 17-hidroksikortikosteroid (17-ketogenic steroids) (card)	B



356	5-Hydroxyindole acetic acid/serotonin test system (card)	Alat uji <i>5-hydroxyindoleacetic acid</i> (5-HIAA)/ Alat uji Serotonin (card)	B
357	17-Hydroxyprogesterone test system (card)	Alat uji 17-OH progesteron (17-OHP)/ alat uji 17-hidroksiprogesteron (card)	B
358	Hydroxyproline test system (card)	Alat uji hidroksiprolin (card)	B
359	Immunoreactive insulin test system (card)	Alat uji insulin immunoreaktif (card)	B
360	Iron (non-heme) test system (card)	Alat uji zat besi (non-heme) (card)	B
361	Iron-binding capacity test system (card)	Alat uji kapasitas ikat zat besi (card)	B
362	Isocitric dehydrogenase test system (card)	Alat uji <i>dehydrogenase isocitric</i> (card)	B
363	17-Ketosteroids test system (card)	Alat uji 17-ketosteroid (card)	B
364	Ketones (nonquantitative) test system (card)	Alat uji keton (nonkuantitatif) (card)	B
365	Lactic acid test system (card)	Alat uji asam laktat (card)	B
366	Leucine aminopeptidase test system (card)	Alat uji <i>leusin aminopeptidase</i> (card)	B
367	Lipase test system (card)	Alat uji lipase(card)	B
368	Lipid (total) test system (card)	Alat uji lipid (total) (card)	B
369	Lipoprotein test system (card)	Alat uji lipoprotein (card)	B
370	Luteinizing hormone test system (card)	Alat uji <i>luteinizing hormone</i> (LH)/ alat uji masa subur/ alat uji ovulasi (card)	B
371	Lysozyme (muramidase) test system (card)	Alat uji lisozim (card)	B
372	Magnesium test system (card)	Alat uji magnesium (card)	B
373	Malic dehydrogenase test system (card)	Alat uji enzim <i>malic dehydrogenase</i> (card)	B
374	Mucopolysaccharides (nonquantitative) test system	Alat uji <i>mucopolysaccharides</i> (nonkuantitatif) (card)	B

	(card)		
375	Nitrite (nonquantitative) test system (card)	Alat uji nitrit (nonkuantitatif) (card)	B
376	Nitrogen (amino-nitrogen) test system (card)	Alat uji nitrogen (amino-nitrogen) (card)	B
377	Plasma oncometry test system (card)	Alat uji <i>oncometry plasma</i> (card)	B
378	Ornithine carbamyl transferase test system (card)	Alat uji enzim <i>ornithine carbamyl transferase</i> (OCT) (card)	B
379	Osmolality test system (card)	Alat uji osmolalitas (card)	B
380	Oxalate test system (card)	Alat uji oksalat (card)	B
384	Urinary pH (nonquantitative) test system (card)	Alat uji pH urin (card)	B
385	Urinary phenylketones (nonquantitative) test system (card)	Alat uji fenilketon urin(card)	B
386	6-Phosphogluconate dehydrogenase test system (card)	Alat uji <i>6-phosphogluconate dehydrogenase</i> (6PGD) (card)	B
387	Phosphohexose isomerase test system (card)	Alat uji isomerase fosfoheksosa (card)	B
388	Phospholipid test system (card)	Alat uji fosfolipid (card)	B
389	Phosphorus (inorganic) test system (card)	Alat uji fosfor (anorganik) (card)	B
390	Porphobilinogen test system (card)	Alat uji porphobilinogen (card)	B
391	Porphyrins test system (card)	Alat uji porfirin (card)	B
392	Pregnanediol test system (card)	Alat uji pregnanediol (card)	B
393	Pregnenolone test system (card)	Alat uji <i>pregnenolone</i> (card)	B
394	Progesterone test system (card)	Alat uji progesteron (card)	B
395	Prolactin (lactogen) test system (card)	Alat uji prolaktin (laktogen) (card)	B
396	Protein (fractionation) test system (card)	Alat uji protein (fraksinasi) (card)	B

397	Protein-bound iodine test system (card)	Alat uji iodin yang berikatan dengan protein (card)	B
398	Urinary protein or albumin (nonquantitative) test system (card)	Alat uji albumin atau protein urin (nonkuantitatif) (card)	B
399	Pyruvate kinase test system (card)	Alat uji piruvat kinase (card)	B
400	Pyruvic acid test system (card)	Alat uji asam piruvat (card)	B
401	Sorbitol dehydrogenase test system (card)	Alat uji sorbitol dehidrogenase (card)	B
402	Testosterone test system (card)	Alat uji testosteron (card)	B
403	Triglyceride test system (card)	Alat uji trigliserida (card)	B
404	Triose phosphate isomerase test system (card)	Alat uji triose fosfat isomerase (card)	B
405	Trypsin test system (card)	Alat uji tripsin (card)	B
406	Free tyrosine test system (card)	Alat uji tirosin bebas (card)	B
407	Uric acid test system (card)	Alat uji asam urat (card)	B
408	Urinary calculi (stones) test system (card)	Alat uji batu kemih (card)	B
409	Urinary urobilinogen (nonquantitative) test system (card)	Alat uji urobilinogen urin (nonkuantitatif) (card)	B
410	Uroporphyrin test system (card)	Alat uji <i>uroporphyrin</i> (card)	B
411	Vanilmandelic acid test system (card)	Alat uji <i>vanillylmandelic acid</i> (VMA) (card)	B
412	Vitamin A test system (card)	Alat uji vitamin A (card)	B
413	Vitamin E test system (card)	Alat uji vitamin E (card)	B
414	Xylose test system (card)	Alat uji xilosa (card)	B
415	Estrogens (total, nonpregnancy) test system (kit & cair)	Alat uji estrogen (total, nonpregnancy) (kit & cair)	B
416	Estrone test system (kit & cair)	Alat uji estron (kit & cair)(card)	B
417	Etiocholanolone test system (kit & cair)	Alat uji <i>etiocholanolone</i> (kit & cair)	C
418	Fatty acids test system (kit & cair)	Alat uji asam lemak (kit & cair)	B

419	Follicle-stimulating hormone test system (kit & cair)	Alat uji <i>follicle-stimulating hormone</i> (FSH) (kit & cair)	B
420	Formiminoglutamic acid (FIGLU) test system (kit & cair)	Alat uji <i>formiminoglutamic acid</i> (FIGLU) (kit & cair)	B
421	Galactose test system (kit & cair)	Alat uji galaktosa(kit & cair)	B
422	Gastric acidity test system (kit & cair)	Alat uji keasaman lambung (kit & cair)	B
423	Gastrin test system (kit & cair)	Alat uji gastrin (kit & cair)	B
424	Globulin test system (kit & cair)	Alat uji globulin (kit & cair)	B
425	Glucagon test system (kit & cair)	Alat uji glukagon (kit & cair)	B
426	Gamma-glutamyl transpeptidase and isoenzymes test system (kit & cair)	Alat uji gamma-glutamyl transpeptidase dan isoenzim (kit & cair)	B
427	Glutathione test system (kit & cair)	Alat uji glutation (kit & cair)	B
428	Human growth hormone test system (kit & cair)	Alat uji human growth hormone (HGH)/ alat uji hormon pertumbuhan (kit & cair)	B
429	Histidine test system (kit & cair)	Alat uji histidin (kit & cair)	B
430	17-Hydroxycorticosteroids (17-ketogenic steroids) test system (kit & cair)	Alat uji 17-hidroksikortikosteroid (17-ketogenic steroids)(kit & cair)	B
431	5-Hydroxyindole acetic acid/serotonin test system (kit & cair)	Alat uji <i>5-hydroxyindoleacetic acid</i> (5-HIAA)/ Alat uji Serotonin(kit & cair)	B
432	17-Hydroxyprogesterone test system (kit & cair)	Alat uji 17-OH progesteron (17-OHP)/ Alat uji 17-hidroksiprogesteron (kit & cair)	B
433	Hydroxyproline test system (kit & cair)	Alat uji hidroksiprolin (kit & cair)	B
434	Immunoreactive insulin test system (kit & cair)	Alat uji insulin immunoreaktif (kit & cair)	B
435	Iron (non-heme) test system (kit & cair)	Alat uji besi (non-heme) (kit & cair)	B

436	Iron-binding capacity test system (kit & cair)	Alat uji kapasitas ikat besi (kit & cair)	B
437	Isocitric dehydrogenase test system (kit & cair)	Alat uji <i>dehidrogenase isocitric</i> (kit & cair)	B
438	17-Ketosteroids test system (kit & cair)	Alat uji 17-ketosteroid (kit & cair)	B
439	Lactic acid test system (kit & cair)	Alat uji asam laktat (kit & cair)	B
440	Leucine aminopeptidase test system (kit & cair)	Alat uji <i>leusin aminopeptidase</i> (kit & cair)	B
441	Lipase test system (kit & cair)	Alat uji lipase (kit & cair)	B
442	Lipid (total) test system (kit & cair)	Alat uji lipid (kit & cair)	B
443	Lipoprotein test system (kit & cair)	Alat uji lipoprotein (kit & cair)	B
444	Luteinizing hormone test system (kit & cair)	Alat uji <i>luteinizing hormone (LH)</i> / alat uji masa subur / alat uji ovulasi (kit & cair)	B
445	Lysozyme (muramidase) test system (kit & cair)	Alat uji lisozim (kit & cair)	B
446	Magnesium test system (kit & cair)	Alat uji magnesium (kit & cair)	B
447	Malic dehydrogenase test system (kit & cair)	Alat uji enzim <i>malic dehydrogenase</i> (kit & cair)	B
448	Mucopolysaccharides (nonquantitative) test system (kit & cair)	Alat uji <i>mucopolysaccharides</i> (kit & cair)	B
449	Nitrite (nonquantitative) test system (kit & cair)	Alat uji nitrit (kit & cair)	B
450	Nitrogen (amino-nitrogen) test system (kit & cair)	Alat uji nitrogen (amino-nitrogen) (kit & cair)	B
451	Plasma oncometry test system (kit & cair)	Alat uji <i>oncometry</i> plasma (kit & cair)	B
452	Ornithine carbamyl transferase test system (kit & cair)	Alat uji enzim <i>ornithine carbamyl transferase (OCT)</i> (kit & cair)	B
453	Osmolality test system (kit &	Alat uji osmolalitas (kit & cair)	B

	cair)		
454	Oxalate test system (kit & cair)	Alat uji oksalat (kit & cair)	B
455	Urinary pH (nonquantitative) test system (kit & cair)	Alat uji pH urin (nonkuantitatif) (kit & cair)	B
456	Urinary phenylketones (nonquantitative) test system (kit & cair)	Alat uji fenilketon urin (nonkuantitatif) (kit & cair)	B
457	6-Phosphogluconate dehydrogenase test system (kit & cair)	Alat uji <i>6-phosphogluconate dehydrogenase</i> (6PGD) (kit & cair)	B
458	Phosphohexose isomerase test system (kit & cair)	Alat uji isomerase fosfoheksosa (kit & cair)	B
459	Phospholipid test system (kit & cair)	Alat uji fosfolipid (kit & cair)	B
460	Phosphorus (inorganic) test system (kit & cair)	Alat uji fosfor (anorganik) (kit & cair)	B
461	Porphobilinogen test system (kit & cair)	Alat uji <i>porphobilinogen</i> (kit & cair)	B
462	Porphyrins test system (kit & cair)	Alat uji porfirin (kit & cair)	B
463	Pregnanediol test system (kit & cair)	Alat uji pregnanediol (kit & cair)	B
464	Pregnenolone test system (kit & cair)	Alat uji <i>pregnenolone</i> (kit & cair)	B
465	Progesterone test system (kit & cair)	Alat uji progesteron (kit & cair)	B
466	Prolactin (lactogen) test system (kit & cair)	Alat uji prolaktin (kit & cair)	B
467	Protein (fractionation) test system (kit & cair)	Alat uji protein (fraksinasi) (kit & cair)	B
468	Protein-bound iodine test system (kit & cair)	Alat uji iodin yang terikat dengan protein (kit & cair)	B
469	Urinary protein or albumin (nonquantitative) test system (kit & cair)	Alat uji albumin atau protein urin (nonkuantitatif) (kit & cair)	B

470	Pyruvate kinase test system (kit & cair)	Alat uji piruvat kinase (kit & cair)	B
471	Pyruvic acid test system (kit & cair)	Alat uji asam piruvat (kit & cair)	B
472	Quality control material (assayed and unassayed) (cair)	Reagen kontrol kualitas ( <i>assayed</i> dan <i>unassayed</i> ) (cair)	B
473	Sorbitol dehydrogenase test system (kit & cair)	Alat uji sorbitol dehidrogenase (kit & cair)	B
474	Testosterone test system (kit & cair)	Alat uji testosteron (kit & cair)	B
475	Triglyceride test system (kit & cair)	Alat uji trigliserid (kit & cair)	B
476	Trypsin test system (kit & cair)	Alat uji tripsin (kit & cair)	B
477	Free tyrosine test system (kit & cair)	Alat uji tirosin bebas (kit & cair)	B
478	Uric acid test system (kit & cair)	Alat uji asam urat (kit & cair)	B
479	Urinary calculi (stones) test system (kit & cair)	Alat uji batu kemih (kit & cair)	B
480	Urinary urobilinogen (nonquantitative) test system (kit & cair)	Alat uji urobilinogen urin (nonkuantitatif) (kit & cair)	B
481	Uroporphyrin test system (kit & cair)	Alat uji <i>uroporphyrin</i> (kit & cair)	B
482	Vanilmandelic acid test system (kit & cair)	Alat uji <i>vanilmandelic acid</i> (VMA) (kit & cair)	B
483	Vitamin E test system (kit & cair)	Alat uji vitamin E (kit & cair)	B
484	Xylose test system (kit & cair)	Alat uji xilosa (kit & cair)	B
485	Cholesterol (total) test system	Alat uji kolesterol total	B
486	Ammonia test system	Alat uji amonia	B
487	Uric acid test system	Alat uji asam urat	B
488	Calibrator (card)	Kalibrator (card)	B
489	Pregnanetriol test system (kit & cair)	Alat uji pregnanetriol (kit & cair)	B
490	Pregnanetriol test system (card)	Alat uji pregnanetriol (card)	B
491	Pregnanetriol test system (strip)	Alat uji pregnanetriol (strip)	B

492	Acute kidney injury test system	Alat uji gagal ginjal akut	B
493	Continuous glucose monitor secondary display	Alat monitor glukosa sekunder kontinu	C
494	Insulin therapy adjustment device	Alat pengatur terapi insulin	C
495	Hemoglobin A1c test system	Alat uji hemoglobin A1c	B
496	Total 25-hydroxyvitamin D mass spectrometry test system.	Alat uji total <i>25-hydroxyvitamin D</i> menggunakan spektrofotometer massa	B
497	Potassium test system	Alat uji kalium	B
498	Cardiac allograft gene expression profiling test system	Alat uji profiling karakteristik gen transplantasi jantung	C

01. Peralatan Kimia Klinik dan Toksikologi Klinik

02. Peralatan Laboratorium Klinik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	General purpose laboratory equipment labeled or promoted for a specific medical use (Electrically operated)	Alat laboratorium untuk penggunaan umum (elektrik)	A
002	General purpose laboratory equipment labeled or promoted for a specific medical use (Non electrically operated)	Alat laboratorium untuk penggunaan umum (manual)	A
003	Calculator/data processing module for clinical use	Kalkulator/modul pemroses data untuk tujuan klinis	A
004	Gas liquid chromatography system for clinical use	Kromatografi cair gas untuk tujuan klinis	A
005	High pressure liquid chromatography system for clinical use	Kromatografi cair tekanan tinggi untuk tujuan klinis	A
006	Thin-layer chromatography system for clinical use	Alat uji kromatografi lapis tipis	A



007	Colorimeter, photometer, or spectrophotometer for clinical use	Kolorimeter, fotometer, dan spektrofotometer untuk tujuan klinis	A
008	Flame emission photometer for clinical use	Fotometer nyala emisi untuk tujuan klinis	A
009	Fluorometer for clinical use	Fluorometer untuk tujuan klinis	A
010	Instrumentation for clinical multiplex test systems	Instrumen multi alat uji untuk tujuan klinis	B
011	Pipetting and diluting system for clinical use.	Alat pemipet dan pengencer untuk tujuan klinis	A
012	Refractometer for clinical use. (Electrically Operated)	Refraktometer untuk tujuan klinis (elektrik)	A
013	Refractometer for clinical use. (Non Electrically Operated)	Refraktometer untuk tujuan klinis (manual)	A
014	Atomic absorption spectrophotometer for clinical use	Spektrofotometer absorpsi atom untuk tujuan klinis	A
015	Mass spectrometer for clinical use	Spektrometer massa untuk tujuan klinis	A
016	Plasma viscometer for clinical use	Viskometer plasma untuk tujuan klinis	A
017	General purpose laboratory equipment labeled or promoted for a specific medical use	Alat laboratorium untuk penggunaan umum	A
018	Electrolyte analyzer	Alat uji elektrolit	B
019	Phmeter for clinical use	Alat uji pH	B
020	Centrifugal chemistry analyzer for clinical use	Alat analisa kimia sentrifugal untuk tujuan klinis	B
021	Continuous flow sequential multiple chemistry analyzer for clinical use	Alat analisa kimia multi parameter berkesinambungan untuk tujuan klinis	B
022	Discrete photometric chemistry analyzer for clinical use	Alat analisa kimia fotometri diskrit untuk tujuan klinis	B
023	Micro chemistry analyzer for clinical use.	Alat analisa kimia mikro untuk tujuan klinis	B

024	Chromatographic separation material for clinical use (Electrically Operated)	Peralatan pemisah kromatografi untuk tujuan klinis (elektrik)	B
025	Chromatographic separation material for clinical use (Non Electrically Operated)	Peralatan pemisah kromatografi untuk tujuan klinis (non elektrik)	B
026	Beta or gamma counter for clinical use	Alat penghitung beta atau gamma untuk tujuan klinis	B
027	Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use. (Electrically Operated)	Alat pemindai/densitometer untuk tujuan klinis (elektrik)	B
028	Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use. (Non Electrically Operated)	Alat pemindai/densitometer untuk tujuan klinis (non elektrik)	B
029	Electrophoresis apparatus for clinical use	Alat elektroforesis untuk tujuan klinis	B
030	Electrophoresis apparatus for clinical use. (Non Electrically Operated)	Alat elektroforesis untuk tujuan klinis (non elektrik)	B
031	Enzyme analyzer for clinical use	Alat analisa enzim untuk tujuan klinis	B
032	Microtitrator for clinical use	Microtitrator untuk tujuan klinis	B
033	Nephelometer for clinical use	Alat <i>nephelometer</i> untuk tujuan klinis	B
034	Plasma oncometer for clinical use.	<i>Oncometer</i> plasma untuk tujuan klinis	B
035	Osmometer for clinical use.	<i>Osmometer</i> untuk tujuan klinis	B
036	Automated urinalysis system.	Alat uji analisa urin otomatis	B
037	Chromatographic separation material for clinical use	Peralatan pemisah kromatografi untuk tujuan klinis	B
038	Clinical Sample Concentrator	Konsentrator sampel klinis	B
039	Clinical chemistry analyzer	Alat analisa kimia klinis	B

040	High throughput genomic sequence analyzer for clinical use.	Alat uji sekuensing genom untuk tujuan klinis	B
041	Continuous glucose monitor data management system	Alat pengolah data monitor glukosa kontinu	C

01. Peralatan Kimia Klinik dan Toksikologi Klinik

03. Sistem Tes Toksikologi Klinik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Acetaminophen test system (strip & midstream)	Alat uji asetaminofen/parasetamol (strip & midstream)	B
002	Amikacin test system (strip & midstream)	Alat uji amikasin (strip & midstream)	B
003	Alcohol test system (strip & midstream)	Alat uji alkohol (strip & midstream)	B
004	Breath nitric oxide test system (strip & midstream)	Alat uji nitrogen monoksida (NO) pada nafas (strip & midstream)	B
005	Amphetamine test system (strip & midstream)	Alat uji amfetamin (strip & midstream)	B
006	Antimony test system (strip & midstream)	Alat uji antimonat (strip & midstream)	B
007	Arsenic test system (strip & midstream)	Alat uji arsen (strip & midstream)	B
008	Barbiturate test system (strip & midstream)	Alat uji barbiturat (strip & midstream)	B
009	Benzodiazepine test system (strip & midstream)	Alat uji benzodiazepin (strip & midstream)	B
010	Clinical toxicology calibrator (strip & midstream)	Kalibrator toksikologi klinis (strip & midstream)	B
011	Carbon monoxide test system (strip & midstream)	Alat uji karbonmonoksida (strip & midstream)	B

012	Cholinesterase test system (strip & midstream)	Alat uji kolinesterase (strip & midstream)	A
013	Cocaine and cocaine metabolite test system (strip & midstream)	Alat uji kokain dan metabolit kokain (strip & midstream)	B
014	Codeine test system (strip & midstream)	Alat uji kodein (strip & midstream)	B
015	Digitoxin test system (strip & midstream)	Alat uji digitoksin (strip & midstream)	B
016	Digoxin test system (strip & midstream)	Alat uji digoksin (strip & midstream)	B
017	Diphenylhydantoin test system (strip & midstream)	Alat uji difenilhidantoin (strip & midstream)	B
018	Drug metabolizing enzyme genotyping system (strip & midstream)	Alat uji genotipe enzim metabolisme obat (strip&midstream)	C
019	Ethosuximide test system (strip & midstream)	Alat uji etosuksinat (strip & midstream)	B
020	Gentamicin test system (strip & midstream)	Alat uji gentamisin (strip & midstream)	B
021	Kanamycin test system (strip & midstream)	Alat uji kanamisin (strip & midstream)	B
022	Lead test system (strip & midstream)	Alat uji timbal (strip & midstream)	B
023	Lidocaine test system (strip & midstream)	Alat uji lidokain (strip & midstream)	B
024	Lithium test system (strip & midstream)	Alat uji litium (strip & midstream)	B
025	Lysergic acid diethylamide (LSD) test system (strip & midstream)	Alat uji LSD (strip & midstream)	B
026	Methamphetamine test system(strip & midstream)	Alat uji metamfetamin/ sabu (strip & midstream)	B
027	Methadone test system (strip & midstream)	Alat uji metadon (strip & midstream)	B
028	Methaqualone test system (strip & midstream)	Alat uji metakualon/MQL (strip & midstream)	B

029	Morphine test system (strip & midstream)	Alat uji morfin/heroin (strip & midstream)	B
030	Neuroleptic drugs radioreceptor assay test system (strip & midstream)	Alat uji radioreseptor obat neuroleptik (strip&midstream)	B
031	Opiate test system (strip & midstream)	Alat uji opiat (strip & midstream)	B
032	Phenobarbital test system (strip & midstream)	Alat uji fenobarbital (strip & midstream)	B
033	Phenothiazine test system (strip & midstream)	Alat uji fenotiazin (strip & midstream)	B
034	Primidone test system (strip & midstream)	Alat uji primidon (strip & midstream)	B
035	Propoxyphene test system (strip & midstream)	Alat uji propoksifen/ alat uji PPX (strip & midstream)	B
036	Salicylate test system (strip & midstream)	Alat uji salisilat (strip & midstream)	B
037	Sirolimus test system (strip & midstream)	Alat uji sirolimus (strip & midstream)	C
038	Sulfonamide test system (strip & midstream)	Alat uji sulfonamida (strip & midstream)	A
039	Cannabinoid test system (strip & midstream)	Alat uji kanabinoid (strip & midstream)	B
040	Theophylline test system (strip & midstream)	Alat uji teofilin (strip & midstream)	B
041	Tobramycin test system (strip & midstream)	Alat uji tobramisin (strip & midstream)	B
042	Tricyclic antidepressant drugs test system (strip & midstream)	Alat uji antidepresan trisiklik (TCA) (strip & midstream)	B
043	Vancomycin test system (strip & midstream)	Alat uji vankomisin (strip & midstream)	B
044	Acetaminophen test system (card)	Alat uji asetaminofen/parasetamol (card)	B
045	Amikacin test system (card)	Alat uji amikasin (card)	B
046	Alcohol test system(card)	Alat uji alkohol (card)	B

047	Breath-alcohol test system	Alat uji alkohol pada nafas	A
048	Breath nitric oxide test system(card)	Alat uji nitrogen monoksida (NO) pada nafas (card)	B
049	Amphetamine test system(card)	Alat uji amfetamin (card)	B
050	Barbiturate test system(card)	Alat uji barbiturat (card)	B
051	Benzodiazepine test system(card)	Alat uji benzodiazepin (card)	B
052	Clinical toxicology calibrator (card)	Kalibrator toksikologi klinis (card)	B
053	Cholinesterase test system(card)	Alat uji kolinesterase (card)	A
054	Cocaine and cocaine metabolite test system(card)	Alat uji kokain dan metabolit kokain (card)	B
055	Codeine test system(card)	Alat uji kodein (card)	B
056	Digitoxin test system(card)	Alat uji digitoksin (card)	B
057	Digoxin test system(card)	Alat uji digoksin (card)	B
058	Diphenylhydantoin test system(card)	Alat uji difenilhidantoin (card)	B
059	Drug metabolizing enzyme genotyping system(card)	Alat uji genotipe enzim metabolisme obat (card)	C
060	Ethosuximide test system(card)	Alat uji ethosuximide (card)	B
061	Gentamicin test system(card)	Alat uji gentamisin (card)	B
062	Kanamycin test system(card)	Alat uji kanamisin (card)	B
063	Lead test system(card)	Alat uji timbal (card)	B
064	Lidocaine test system(card)	Alat uji lidokain (card)	B
065	Lithium test system(card)	Alat uji litium (card)	B
066	Lysergic acid diethylamide (LSD) test system(card)	Alat uji LSD (card)	B
067	Methamphetamine test system (card)	Alat uji metamfetamin/ sabu (card)	B
068	Methadone test system (card)	Alat uji metadon (card)	B
069	Methaqualone test system (card)	Alat uji metakuilon/MQL (card)	B
070	Morphine test system (card)	Alat uji morfin/ Heroin (card)	B
071	Neuroleptic drugs radioreceptor assay test system (card)	Alat uji radioreseptor obat neuroleptik (card)	B
072	Opiate test system (card)	Alat uji opiat (Card)	B
073	Phenobarbital test system (card)	Alat uji fenobarbital	B
074	Phenothiazine test system (card)	Alat uji fenotiazin (card)	B

075	Primidone test system (card)	Alat uji primidon (card)	B
076	Propoxyphene test system (card)	Alat uji propoksifen (PPX) (card)	B
077	Salicylate test system (card)	Alat uji salisilat (card)	B
078	Sirolimus test system (card)	Alat uji sirolimus (card)	C
079	Sulfonamide test system (card)	Alat uji sulfonamid (card)	A
080	Cannabinoid test system (card)	Alat uji kanabinoid (card)	B
081	Theophylline test system (card)	Alat uji teofilin (card)	B
082	Tobramycin test system (card)	Alat uji tobramisin (card)	B
083	Tricyclic antidepressant drugs test system(card)	Alat uji antidepresan trisiklik (TCA) (card)	B
084	Vancomycin test system (card)	Alat uji vankomisin (card)	B
085	Acetaminophen test system (kit & cair)	Alat uji asetaminofen/ alat uji parasetamol	B
086	Amikacin test system (kit & cair)	Alat uji amikasin (kit & cair)	B
087	Alcohol test system (kit & cair)	Alat uji alkohol (kit & cair)	B
088	Breath-alcohol test system (kit & cair)	Alat uji alkohol pada nafas (kit & cair)	A
089	Breath nitric oxide test system (kit & cair)	Alat uji nitrogen monoksida (NO) pada nafas (kit & cair)	B
090	Amphetamine test system (kit & cair)	Alat uji amfetamin (kit & cair)	B
091	Barbiturate test system (kit & cair)	Alat uji barbiturat (kit & cair)	B
092	Benzodiazepine test system (kit & cair)	Alat uji benzodiazepin (kit & cair)	B
093	Clinical toxicology calibrator (kit & cair)	Kalibrator toksikologi klinis (kit & cair)	B
094	Cholinesterase test system (kit & cair)	Alat uji kolinesterase (kit & cair)	A
095	Cocaine and cocaine metabolite test system (kit & cair)	Alat uji kokain dan metabolit kokain (kit & cair)	B
096	Codeine test system (kit & cair)	Alat uji kodein (kit & cair)	B
097	Digitoxin test system (kit & cair)	Alat uji digitoksin (kit & cair)	B
098	Digoxin test system (kit & cair)	Alat uji digoksin (kit & cair)	B

099	Diphenylhydantoin test system (kit & cair)	Alat uji difenilhidantoin (kit & cair)	B
100	Drug metabolizing enzyme genotyping system (kit & cair)	Alat uji genotipe enzim metabolisme obat (kit & cair)	C
101	Ethosuximide test system (kit & cair)	Alat uji ethosuximide	B
102	Gentamicin test system (kit & cair)	Alat uji gentamisin (kit & cair)	B
103	Kanamycin test system (kit & cair)	Alat uji kanamisin (kit & cair)	B
104	Lead test system (kit & cair)	Alat uji timbal (kit & cair)	B
105	Lidocaine test system (kit & cair)	Alat uji lidokain (kit & cair)	B
106	Lithium test system (kit & cair)	Alat uji litium (kit & cair)	B
107	Mercury test system (kit & cair)	Alat uji merkuri (kit & cair)	B
108	Methamphetamine test system (kit & cair)	Alat uji metamfetamin/ sabu (kit & cair)	B
109	Methadone test system (kit & cair)	Alat uji metadon (kit & cair)	B
110	Methaqualone test system (kit & cair)	Alat uji metakuilon/MQL (kit & cair)	B
111	Morphine test system (kit & cair)	Alat uji morfin/ heroin (kit & cair)	B
112	Neuroleptic drugs radioreceptor assay test system (kit & cair)	Alat uji radioreseptor obat neuroleptik (kit & cair)	B
113	Opiate test system (kit & cair)	Alat uji opiat (kit & cair)	B
114	Phenobarbital test system (kit & cair)	Alat uji fenobarbital	B
115	Phenothiazine test system (kit & cair)	Alat uji fenotiazin (kit & cair)	B
116	Primidone test system (kit & cair)	Alat uji primidon (kit & cair)	B
117	Quinine test system (kit & cair)	Alat uji kina (kit & cair)	B
118	Salicylate test system (kit & cair)	Alat uji salisilat (kit & cair)	B
119	Sirolimus test system (kit & cair)	Alat uji sirolimus (kit & cair)	C
120	Cannabinoid test system (kit & cair)	Alat uji kanabinoid (kit & cair)	B



121	Theophylline test system (kit & cair)	Alat uji teofilin (kit & cair)	B
122	Tobramycin test system (kit & cair)	Alat uji tobramisin (kit & cair)	B
123	Tricyclic antidepressant drugs test system (kit & cair)	Alat uji antidepresan trisiklik (TCA) (kit & cair)	B
124	Vancomycin test system (kit & cair)	Alat uji vankomisin (kit & cair)	B
125	Multi parameter clinical toxicology test system	Alat uji toksikologi klinis multiparameter	C
126	Lithium test system	Alat uji litium	B
127	Paraquat Test Syatem	Alat uji <i>paraquat</i>	C
128	Topiramate test system	Alat uji <i>topiramate</i>	B
129	Chloral hydrate test system	Alat uji kloralhidrat	B
130	Zinc test system	Alat uji zink/ alat uji seng	B
131	Breath-alcohol test system (strip & midstream)	Alat uji alkohol pada nafas (strip & midstream)	A
132	Clinical toxicology control material (strip)	Kontrol toksikologi klinis (strip)	B
133	Mercury test system (strip & midstream)	Alat uji merkuri (strip & midstream)	B
134	Quinine test system (strip & midstream)	Alat uji kina (strip & midstream)	B
135	Antimony test system (card)	Alat uji antimon (card)	B
136	Arsenic test system (card)	Alat uji arsen (card)	B
137	Carbon monoxide test system (card)	Alat uji karbonmonoksida (card)	B
138	Mercury test system (card)	Alat uji merkuri (card)	B
139	Quinine test system (card)	Alat uji kina (card)	B
140	Antimony test system (kit & cair)	Alat uji antimon (kit & cair)	B
141	Arsenic test system (kit & cair)	Alat uji arsen (kit & cair)	B
142	Carbon monoxide test system (kit & cair)	Alat uji karbonmonoksida (kit & cair)	B
143	Clinical toxicology control material (kit & cair)	Kontrol toksikologi klinis (kit & cair)	B

144	Lysergic acid diethylamide (LSD) test system (kit & cair)	Alat uji LSD (kit & cair)	B
145	Propoxyphene test system (kit & cair)	Alat uji propoksifen (PPX) (kit & cair)	B
146	Sulfonamide test system (kit & cair)	Alat uji sulfonamida (kit & cair)	A
147	Organophosphate test system	Alat uji organofosfat	B
148	Reagents for molecular diagnostic instrument test systems	Pereaksi untuk alat uji diagnostik molekular	B

## 02. Peralatan Hematologi dan Patologi

### 01. Pewarna Biologi

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Dye and chemical solution stains.	Pewarna dan larutan zat warna kimia	A
002	Immunohistochemistry reagents and kits (Qualitative).	Reagen dan kit imunohistokimia (IHC), uji pewarnaan antibodi / antigen (kualitatif)	A
003	Immunohistochemistry reagents and kits (Quantitative).	Reagen dan kit imunohistokimia (IHC), uji pewarnaan antibodi / antigen (kuantitatif)	B
004	Cervical intraepithelial neoplasia (CIN) test system	Alat uji CIN	B

## 02. Peralatan Hematologi dan Patologi

### 02. Produk Kultur Sel dan Jaringan

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Synthetic cell and tissue culture	Media/agar sintetik untuk	A

	media and components	kultur sel & jaringan	
002	Cell and tissue culture supplies and equipment.	Alat-alat untuk kultur sel & jaringan	A
003	Chromosome culture kit.	Kit kultur kromosom	A
004	Cultured animal and human cells.	Kultur sel hewan dan manusia	A
005	Mycoplasma detection media and components.	Media dan komponen deteksi <i>mycoplasma</i>	A
006	Animal and human sera.	Serum dari hewan dan manusia	A
007	Balanced salt solutions or formulations.	<i>Hanks balanced salt solution</i> (HBSS)	A
008	Hematopoietic Stem Cell test system	Alat uji hematopoietik sel punca	C
009	Somatic Gene Mutation Detection System	Alat deteksi mutasi gen somatik	C

## 02. Peralatan Hematologi dan Patologi

### 03. Peralatan dan Aksesoris Patologi

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Tissue processing equipment (Parts and accessories including printed circuit assemblies for product of heading 90.27, other than for gas or smoke analysis apparatus and microtomes)	<i>Tissue embedding, microtome</i> (part dan aksesoris)	A
002	Tissue processing equipment (electrically operated)	<i>Tissue embedding, microtome</i> (elektrik)	A
003	Tissue processing equipment (lain-lain)	<i>Tissue embedding, microtome</i> (lain lain)	A
004	Specimen transport and storage container.	Wadah penyimpanan dan transport specimen	A
005	OTC test sample collection systems for drugs of abuse	Wadah penyimpanan sampel <i>drugs of abuse tests</i>	A

	testing.		
006	Cytocentrifuge.	<i>Cytocentrifuge</i>	A
007	Device for sealing microsections. (Electrically Operated)	Alat <i>sealing microsections</i> (elektrik)	A
008	Device for sealing microsections. (Non Electrically Operated)	Alat <i>sealing microsections</i> (non- elektrik)	A
009	Automated tissue processor.	Alat pemroses jaringan otomatis	A
010	Microscopes and accessories	Mikroskop dan aksesoris	A
011	Tissue processing equipment	<i>Tissue embedding, microtome</i>	A
012	Automated slide stainer.	Alat pewarnaan otomatis untuk imunohistokimia	B
013	Whole slide imaging system	Alat pencitraan <i>slide</i> patologi	B

## 02. Peralatan Hematologi dan Patologi

### 04. Pereaksi Penyedia Spesimen

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	General purpose reagent.	Reagen umum ( <i>buffer, cleaner</i> )	A
002	Analyte specific reagents.	Reagen analit khusus	B
003	Enzyme preparations.	Enzim untuk preparasi	A

## 02. Peralatan Hematologi dan Patologi

### 05. Peralatan Hematologi Otomatis dan Semi Otomatis

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Automated cell counter.	Alat hematologi otomatis penghitung sel	B
002	Automated differential cell counter.	Alat hematologi otomatis penghitung diferensiasi sel	B
003	Automated cell-locating device.	Alat pendeteksi lokasi sel otomatis	B
004	Red cell indices device.	Indikator sel darah merah	B

005	Microsedimentation centrifuge.	Sentrifus mikrosedimentasi	A
006	Coagulation instrument.	Alat koagulasi	C
007	Multipurpose system for in vitro coagulation studies.	Alat studi koagulasi dan uji faktor koagulasi	B
008	Multipurpose system for in vitro coagulation studies (for reagent & control)	Alat studi koagulasi dan uji faktor koagulasi (untuk reagen & kontrol)	B
009	Automated hematocrit instrument.	Alat uji hematokrit otomatis	B
010	Automated hemoglobin system.	Alat uji hemoglobin otomatis	B
011	Automated hemoglobin system (for reagent & control)	Alat uji hemoglobin otomatis (untuk reagen & kontrol)	B
012	Automated heparin analyzer.	Alat uji heparin otomatis	B
013	Automated platelet aggregation system.	Alat uji agregasi platelet/trombosit otomatis	B
014	Automated sedimentation rate device.	Alat uji laju endap darah (ESR /LED)	A
015	Blood volume measuring device.	Alat pengukur volume darah	B
016	Automated blood cell diluting apparatus.	Peralatan pengencer sel darah otomatis	B
017	Automated slide spinner.	Pemutar <i>slide</i> otomatis	B
018	Semi automated blood extractor	Alat semi otomatis pemisah darah	B

## 02. Peralatan Hematologi dan Patologi

### 06. Peralatan Hematologi Manual

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Bleeding time device	Alat pengukur lamanya waktu perdarahan	B
002	Manual blood cell counting device	Alat penghitung sel darah manual	A
003	Occult blood test.(chemical test)	<i>Fecal Occult Blood</i> (FOB) (alat uji kimia)	B
004	Occult blood test.(using spectroscopy)	<i>Fecal Occult Blood</i> (FOB) (dengan spektroskopi)	B

005	Occult blood test.(using microscope)	<i>Fecal Occult Blood (FOB)</i> (dengan mikroskop)	B
006	Platelet adhesion test	PFA system, alat uji adhesi platelet	B
007	Platelet aggregometer	Alat uji agregrasi platelet	B
008	Occult blood test	<i>Fecal Occult Blood (FOB)</i>	B
009	Capillary blood collection tube	Tabung pengumpul darah kapiler	B
010	Capillary blood collection tube (for glass)	Tabung pengumpul darah kapiler (untuk kaca)	B
011	Hematocrit measuring device. (Electrically Operated)	Alat ukur hematokrit (elektrik)	B
012	Hematocrit measuring device. (Non Electrically Operated)	Alat ukur hematokrit (non elektrik)	B
013	Osmotic fragility test.	Tes kerapuhan osmotik	B
014	Erythrocyte sedimentation rate test (other, electrically operated)	Alat uji laju sedimentasi eritrosit (elektrik)	B
015	Erythrocyte sedimentation rate test (other, manually operated)	Alat uji laju sedimentasi eritrosit (manual)	B

## 02. Peralatan Hematologi dan Patologi

### 07. Paket dan Kit Hematologi

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Antithrombin III assay	Alat uji anti thrombin III (ATIII)	B
002	Red blood cell enzyme assay	Alat uji sel darah merah	B
003	Activated whole blood clotting time tests	Alat uji waktu koagulasi darah (ACT)	C
004	Erythropoietin assay	Alat uji <i>erythropoietin</i> (EPO)	B
005	Euglobulin lysis time tests	Alat uji waktu lisis euglobulin (ELT)	B
006	Factor V Leiden DNA mutation detection systems	Alat uji mutasi DNA <i>factor V Leiden</i>	C
007	Factor deficiency test	Alat uji faktor defisiensi	B

008	Fibrin monomer paracoagulation test	Alat uji parakoagulasi monomer fibrin	B
009	Fibrinogen/fibrin degradation products assay	Alat uji produk degradasi fibrinogen/fibrin, D-Dimer	C
010	Fibrinogen determination system	Alat uji determinasi fibrinogen (FIB)	B
011	Erythrocytic glucose-6-phosphate dehydrogenase assay	Alat uji G6PD	B
012	Glutathione reductase assay	Alat uji <i>glutathione reductase</i> (GR)	B
013	Hemoglobin A[bdi2] assay	Alat uji hemoglobin A[bdi2], alat uji thalassemia	B
014	Abnormal hemoglobin assay	Alat uji hemoglobin abnormal	B
015	Carboxyhemoglobin assay	Alat uji <i>carboxyhemoglobin</i>	B
016	Electrophoretic hemoglobin analysis system	Alat uji hemoglobin elektroforesis (Hb ELP)	B
017	Fetal hemoglobin assay	Alat uji fetal hemoglobin (HbF)	B
018	Glycosylated hemoglobin assay	Alat uji HbA1c	B
019	Sulfhemoglobin assay	Alat uji sulfhemoglobin (SulfHb)	B
020	Whole blood hemoglobin assays	Alat uji hemoglobin (Hb)	B
021	Heparin assay	Alat uji heparin	B
022	Platelet factor 4 radioimmunoassay	Alat uji faktor 4 platelet <i>radioimmunoassay</i>	B
023	Prothrombin consumption test	Alat uji pemakaian protrombin	B
024	Prothrombin-proconvertin test and thrombotest	Alat uji <i>prothrombin-proconvertin</i> dan <i>thrombotest</i>	B
025	Prothrombin time test	Alat uji waktu protrombin (PT)	C
026	Sickle cell test	Alat uji sel sabit	B
027	Thrombin time test	Alat uji waktu trombin	B
028	Partial thromboplastin time tests	Alat uji PTT (APTT)	C
029	Adenosine triphosphate release assay	Alat uji pelepasan adenosin trifosfat	C
030	Leukocyte alkaline phosphatase test	Alat uji alkali fosfatase leukosit	B
031	Leukocyte peroxidase test	Alat uji peroksidase leukosit	B

032	Thromboplastin generation test	Alat uji pertumbuhan tromboplastin	B
033	Flow cytometric test system for hematopoietic neoplasms	Alat uji aliran sitometri untuk neoplasma hematopoietik	C

02. Peralatan Hematologi dan Patologi

08. Pereaksi Hematologi

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Bothrops atrox reagent	Reagen <i>bothrops atrox</i>	B
002	Calibrator for cell indices	Kalibrator untuk indikator sel	B
003	Calibrator for hemoglobin or hematocrit measurement	Kalibrator untuk pengukuran hemoglobin atau hematokrit	B
004	Calibrator for platelet counting	Kalibrator untuk menghitung platelet	B
005	Calibrator for red cell and white cell counting	Kalibrator untuk menghitung sel darah merah and sel darah putih	B
006	Hematology quality control mixture	Kontrol untuk hematologi	B
007	Blood cell diluents	Pengencer sel darah	B
008	Lymphocyte separation medium	Media pemisahan limfosit	B
009	Red cell lysing reagent	Reagen pelisis sel darah merah	B
010	Russell viper venom reagent	Reagen bisa ular <i>Russell viper</i>	B

02. Peralatan Hematologi dan Patologi

09. Produk yang digunakan dalam pembuatan sediaan darah dan sediaan berasal dari darah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Blood bank supplies.	Perlengkapan bank darah	A



002	Empty container for the collection and processing of blood and blood components.	Wadah kosong untuk pengumpulan dan pengolahan darah serta komponennya	C
003	Vacuum-assisted blood collection system.	Wadah pengumpul darah vakum	B
004	Processing system for frozen blood	Alat pengolah darah beku	B
005	Automated blood grouping and antibody test system	Alat uji golongan darah dan antibodi otomatis	C
006	Blood grouping view box	Alat untuk melihat penggolongan darah	A
007	Blood and plasma warming device	Alat penghangat darah dan plasma	B
008	Blood bank centrifuge for in vitro diagnostic use	Alat sentrifus untuk penggunaan diagnostik in vitro	A
009	Automated cell-washing centrifuge for immuno-hematology	Alat sentrifus untuk pencucian sel otomatis	C
010	Automated Coombs test systems.	Alat uji <i>Coombs</i> otomatis	C
011	Copper sulfate solution for specific gravity determinations	Alat uji hemoglobin dengan metode determinasi spesifik gravitasi <i>copper sulphate</i>	A
012	Stabilized enzyme solution	Larutan enzim penstabil	B
013	Lectins and protectins	Lektin dan protektin	C
014	Environmental chamber for storage of platelet concentrate	Wadah penyimpanan konsentrat platelet	C
015	Potentiating media for in vitro diagnostic use	Media potensial untuk penggunaan diagnostik in vitro	C
016	Quality control kit for blood banking reagents	Kontrol untuk reagen bank darah	B
017	Blood storage refrigerator and blood storage freezer	Lemari pendingin tempat penyimpanan dan pembekuan darah	B
018	Heat-sealing device	Alat penyegel dengan panas, <i>thermosealer</i>	A
019	Transfer set	Alat transfer darah	B

020	Automated blood cell separator	Alat pemisah sel darah otomatis	B
021	Automated blood cell separator for therapeutic purposes	Alat pemisah sel darah otomatis untuk terapeetik	C
022	Blood group substances of nonhuman origin for in vitro diagnostic use	Alat uji deteksi antigen pada sel darah, identifikasi antibodi golongan darah	C
023	Blood mixing devices and blood weighing devices	Alat pencampur dan penimbang darah	B
024	Cell-freezing apparatus and reagents for in vitro diagnostic use	Alat pembekuan sel dan reagen untuk penggunaan diagnostik in vitro	B

## 02. Peralatan Hematologi dan Patologi

### 10. Produk yang Digunakan Dalam Proses Produksi Sel dan Jaringan, Serta Produk Berbasis Sel dan Jaringan Manusia

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Cord blood processing system and storage container	Sistem pengolahan dan wadah penyimpanan darah tali pusat	B

## 03. Peralatan Imunologi dan Mikrobiologi

### 01. Peralatan Diagnostika

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Antimicrobial susceptibility test disc	Alat uji sensitivitas antimikroba	B
002	Antimicrobial susceptibility test powder	Alat uji sensitivitas antimikroba (serbuk)	B

003	Fully automated short-term incubation cycle antimicrobial susceptibility system	Alat untuk identifikasi mikroba dan uji sensitivitas antibiotika	B
004	Culture medium for antimicrobial susceptibility tests	Media kultur untuk uji sensitivitas antimikroba.	B

### 03. Peralatan Imunologi dan Mikrobiologi

#### 02. Peralatan Mikrobiologi

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Anaerobic chamber	Wadah / ruang anaerob	A
002	Multipurpose culture medium	Media kultur serbaguna	A
003	Differential culture medium	Media kultur diferensial	A
004	Enriched culture medium	Media kultur yang diperkaya	A
005	Microbiological assay culture medium	Media kultur uji mikrobiologis	A
006	Selective culture medium	Media kultur selektif	A
007	Transport culture medium	Media kultur transport	A
008	Culture medium for pathogenic <i>Neisseria</i> spp	Media kultur untuk <i>Neisseria spp</i> patogen	C
009	Automated medium dispensing and stacking device	Alat untuk mengisi dan menyusun media kultur otomatis	A
010	Supplement for culture media	Suplemen untuk media kultur	A
011	Microtiter diluting and dispensing device	Mikrotiter untuk pengencer dan penyaluran	A
012	Microbiological incubator	Inkubator mikrobiologi	A
013	Microbial growth monitor (Electrically Operated)	Alat pemantau pertumbuhan mikroba (elektrik)	A
014	Microbial growth monitor (Non Electrically Operated)	Alat pemantau pertumbuhan mikroba (non elektrik)	A
015	Wood's fluorescent lamp	Lampu fluoresensi Wood, <i>Wood's lamp</i>	A
016	Microorganism differentiation and identification device	Perangkat diferensiasi dan identifikasi mikroorganisme	B

		(Filariasis)	
017	Automated zone reader	Pembaca zona otomatis	A
018	Microbiological specimen collection and transport device	Wadah penyimpanan dan transport untuk spesimen mikrobiologi	A
019	Microbial growth monitor	Alat pemantau pertumbuhan mikroba	A
020	Staphylococcal typing bacteriophage	Alat uji tipe <i>staphylococcal bacteriophage</i>	B
021	Coagulase plasma	Plasma koagulasi	B
022	Automated colony counter	Alat penghitung koloni otomatis	B
023	Manual colony counter	Alat penghitung koloni manual	B
024	Oxidase screening test for gonorrhoea	Alat uji penapisan oksidase untuk gonore	C
025	Quality control kit for culture media	Alat kontrol kualitas untuk kultur media	B
026	Gas-generating device	Peralatan Pembangkit Gas	B
027	Automated image assessment system for microbial colonies on solid culture media	Alat uji koloni mikroba pada kultur media	B
028	Streptococcus spp. nucleic acid-based assay	Alat uji deteksi asam nukleat <i>Streptococcus spp.</i>	C

### 03. Peralatan Imunologi dan Mikrobiologi

#### 03. Pereaksi Serologi

Kode	Jenis Produk	Sinonim	Kelas
001	Adenovirus serological reagents	Reagen serologi adenovirus	A
002	Aspergillus spp. serological reagents	Reagen serologi Aspergillus spp.	A
003	Beta-glucan serological assays	Alat uji serologi beta-glukan	B

004	Blastomyces dermatitidis serological reagents	Reagen serologi Blastomyces dermatitidis	B
005	Brucella spp. serological reagents	Reagen serologi Brucella spp.	B
006	Coccidioides immitis serological reagents	Reagen serologi Coccidioides immitis	B
007	Corynebacterium spp. serological reagents	Reagen serologi Corynebacterium spp.	A
008	Cryptococcus neoformans serological reagents	Reagen serologi Cryptococcus neoformans	C
009	Cytomegalovirus serological reagents	Reagen serologi sitomegalovirus	C
010	Endotoxin assay	Alat uji endotoksin	B
011	Entamoeba histolytica serological reagents	Reagen serologi Entamoeba histolytica	B
012	Flavobacterium spp. serological reagents	Reagen serologi Flavobacterium spp.	A
013	Francisella tularensis serological reagents	Reagen serologi Francisella tularensis	B
014	Haemophilus spp. serological reagents	Reagen serologi Haemophilus spp.	B
015	Herpes simplex virus serological assays	Alat uji serologi virus herpes simpleks	C
016	Hepatitis A virus (HAV) serological assays	Alat uji serologi virus Hepatitis A (HAV)	B
017	Histoplasma capsulatum serological reagents	Reagen serologi Histoplasma capsulatum	B
018	Reagents for detection of specific novel influenza A viruses	Reagen deteksi virus influenza A Jenis baru	B
019	Leptospira spp. serological reagents	Reagen serologi Leptospira spp	B
020	Neisseria spp. direct serological test reagents	Reagen serologi Neisseria spp	C
021	Plasmodium species antigen detection assays	Alat uji deteksi antigen spesies Plasmodium (ex: malaria)	B

022	Pseudomonas spp. serological reagents	Reagen serologi Pseudomonas spp	B
023	Rabiesvirus immunofluorescent reagents	Reagen imunofluoresen Virus Rabies	B
024	Rubella virus serological reagents	Reagen serologi virus Rubella	C
025	Salmonella spp. serological reagents	Reagen Serologi Salmonella spp	B
026	Shigella spp. serological reagents	Reagen serologi Shigella spp	B
027	Toxoplasma gondii serological reagents	Reagen serologi Toxoplasma gondii	C
028	Treponema pallidum nontreponemal test reagents	Reagen uji treponema pallidum nontreponemal	C
029	Treponema pallidum treponemal test reagents	Reagen uji treponema pallidum treponemal	C
030	Trypanosoma spp. serological reagents	Reagen serologi Trypanosoma spp	A
031	Varicella-zoster virus serological reagents	Reagen serologi virus Varicella-zoster	B
032	Vibrio cholerae serological reagents	Reagen serologi Vibrio cholerae	B
033	West Nile virus serological reagents.	Reagen serologi virus West Nile	C
034	Respiratory viral panel multiplex nucleic acid assay	Alat uji asam nukleat multiplex panel respiratory viral	B
035	Multiparameter serological reagents	Alat uji serologi multiparameter	C
036	Dengue virus nucleic acid amplification test reagents	Alat uji asam nukleat virus dengue	C
037	Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures	Alat uji Multiplex asam nukleat untuk mendeteksi mikroorganisme dan marker dari kultur darah positif	C
038	Clostridium difficile toxin gene amplification assay	Alat uji Clostridium difficile	B

039	John Cunningham Virus serological reagents	Alat uji virus JohnCunningham	C
040	Nucleic acid-based in vitro diagnostic devices for the detection of Mycobacterium tuberculosis complex (MTB-complex) and the genetic mutations associated with MTB-complex antibiotic resistance in respiratory specimens (kit & cair)	Alat uji MTB-Complex (kit dan cair)	B
041	Nucleic acid-based in vitro diagnostics devices for the detection of Mycobacterium tuberculosis complex in respiratory specimens (kit & cair)	Asam nukleat untuk mendeteksi mycobacterium TB (kit dan cair)	B
042	Gastrointestinal microorganism multiplex nucleic acid-based assay	Alat uji multi mikroorganisme gastrointestinal	B
043	Procalcitonin test system	Alat uji Procalcitonin	B
044	Mass spectrometer system for clinical use for the identification of microorganism	Spektrometer massa untuk tujuan klinis untuk identifikasi mikroba	B
045	Parvovirus B19 serological test system	Alat uji Serologi Parvovirus B19	B
046	Acinetobacter calcoaceticus serological reagents	Reagen serologi Acinetobacter calcoaceticus	B
047	Arizona spp. serological reagents	Reagen Serologi Arizona Spp	B
048	Bordetella spp. serological reagents	Reagen Serologi Bordetella Spp	B
049	Campylobacter fetus serological reagents	Reagen Serologi Campylobacter Fetus	B
050	Chlamydia serological reagents	Reagen Serologi Chlamydia	C
051	Citrobacter spp. serological reagents	Reagen Serologi Citrobacter Spp	B
052	Coxsackievirus serological reagents	Reagen Serologi Coxsackievirus	B

053	Echinococcus spp. serological reagents	Reagen Serologi Echinococcus Spp	B
054	Echovirus serological reagents	Reagen Serologi Echovirus	B
055	Epstein-Barr virus serological reagents	Reagen Serologi Evirus Epstein-Barr	C
056	Equine encephalomyelitis virus serological reagents	Reagen Serologi Encephalomyelitis Equine	B
057	Erysipelothrix rhusiopathiae serological reagents	Reagen Serologi Erysipelothrix Rhusiopathiae	B
058	Escherichia coli serological reagents	Reagen Serologi Escherichia Coli	B
059	Gonococcal antibody test (GAT)	Reagen Serologi Gonococcal Antibody (GAT)	C
060	Influenza virus serological reagents	Reagen Serologi Influenza Virus	B
061	Klebsiella spp. serological reagents	Reagen Serologi Klebsiella Spp	B
062	Listeria spp. serological reagents	Reagen Serologi Listeria Spp	C
063	Lymphocytic choriomeningitis virus serological reagents	Reagen Serologi Virus Lymphocyticchoriomeningitis	B
064	Mycobacterium tuberculosis immunofluorescent reagents	Reagen Immunofluorescent Mycobacterium Tuberculosis	C
065	Mycoplasma spp. serological reagents	Reagen Serologi Mycoplasma Spp	B
066	Mumps virus serological reagents	Reagen Serologi Virus Mumps	B
067	Parainfluenza virus serological reagents	Reagen Serologi Virus Parainfluenza	B
068	Poliovirus serological reagents	Reagen Serologi Poliovirus	B
069	Proteus spp. (Weil-Felix) serological reagents	Reagen Serologi Proteus Spp	B
070	Reovirus serological reagents	Reagen Serologi Reovirus	B
071	Respiratory syncytial virus serological reagents	Reagen Serologi Virus Respiratory Syncytial	B
072	Rhinovirus serological reagents	Reagen Serologi Rhinovirus	B
073	Rickettsia serological reagents	Reagen Serologi Rickettsia	B



074	Rubeola (measles) virus serological reagents	Reagen Serologi Virus Rubeola (Measles)	B
075	Schistosoma spp. serological reagents	Reagen Serologi Schistosoma Spp	B
076	Serratia spp. serological reagents	Reagen Serologi Serratia Spp	B
077	Sporothrix schenckii serological reagents	Reagen Serologi Sporothrix Schenckii	B
078	Staphylococcus aureus serological reagents	Reagen Serologi Staphylococcus Aureus	B
079	Streptococcus spp. exoenzyme reagents	Reagen Exoenzym Streptococcus Spp	C
080	Streptococcus spp. serological reagents	Reagen Serologi Streptococcus Spp	C
081	Trichinella spiralis serological reagents	Reagen Serologi Trichinella Spiralis	B
082	In vitro human immunodeficiency virus (HIV) drug resistance genotype assay	Reagen Serologi Resistensi Obat HIV	C
083	Dengue virus serological reagents	Reagen serologi virus dengue (DHF)	C
084	Trichomonas vaginalis nucleic acid assay	Alat uji asam nukleat Trichomonas vaginalis	B
085	Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis	Alat uji analit non microbial pada sepsis	B
086	Influenza virus antigen detection test system	Alat uji deteksi Virus Influenza	B
087	Nucleic acid-based device for the amplification, detection, and identification of microbial pathogens directly from whole blood specimens	Alat uji amplifikasi, deteksi dan identifikasi mikroba patogen dari sampel darah	C
088	In vitro diagnostic device for Bacillus spp. Detection	Alat uji deteksi bacillus spp.	C

089	Enterovirus nucleic acid assay	Alat uji asam nukleat enterovirus	C
090	Assayed quality control material for clinical microbiology assays.	Kontrol untuk mikrobiologi	B
091	Device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid.	Alat uji deteksi asam nukleat patogen mikroba dalam dalam cairan serebrospinal	B
092	Device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens.	Alat uji deteksi mikroorganisme dan asam nukleat penanda resistensi dari spesimen pernapasan	B
093	Herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel.	Alat uji asam nukleat virus herpes	C
094	Human immunodeficiency virus (HIV) drug resistance genotyping assay using next generation sequencing technology	Alat uji genotipe resistansi obat HIV	C
095	Norovirus serological reagents	Reagen serologi Norovirus	B

### 03. Peralatan Imunologi dan Patologi

#### 04. Perlengkapan dan Pereaksi Laboratorium Imunologi

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	RNA Preanalytical Systems.	Sistem preanalitik RNA	C
002	Ouchterlony agar plate	Cawan petri agar <i>Ouchterlony</i>	A
003	Radial immunodiffusion plate	Cawan imunodifusi radial	A
004	Automated fluorescence in situ hybridization (FISH) enumeration systems	Sistem enumerasi FISH otomatis	C
005	Immunonephelometer equipment	Peralatan <i>Immunonephelometer</i>	B
006	Complement reagent	Reagen komplemen	B

007	Immunoelectrophoresis equipment. (Electrically Operated)	Peralatan imunoelektroforesis (elektrik)	B
008	Immunoelectrophoresis equipment. (Non Electrically Operated)	Peralatan imunoelektroforesis (non elektrik)	B
009	Immunofluorometer equipment. (Electrically Operated)	Peralatan imunofluorometer (Elektrik)	B
010	Immunofluorometer equipment. (Non Electrically Operated)	Peralatan imunofluorometer (Non Elektrik)	B
011	Immunonephelometer equipment. (Electrically Operated)	Peralatan <i>Immunonephelometer</i> (elektrik)	B
012	Immunonephelometer equipment. (Non Electrically Operated)	peralatan <i>Immunonephelometer</i> (non-elektrik)	B
013	Automated fluorescence in situ hybridization (FISH) enumeration systems. (Electrically Operated)	Alat uji FISH enumerasi secara otomatis (elektrik)	C
014	Automated fluorescence in situ hybridization (FISH) enumeration systems. (Non Electrically Operated)	Alat uji FISH enumerasi secara otomatis (non-elektrik)	C
015	Rocket immunoelectrophoresis equipment. (Electrically Operated)	Peralatan imunoelektroforesis <i>rocket</i> (elektrik)	B
016	Rocket immunoelectrophoresis equipment. (Non Electrically Operated)	Peralatan imunoelektroforesis <i>rocket</i> (non elektrik)	B
017	Support gel.	Gel pendukung	B
018	Immunofluorometer equipment	Peralatan imunofluorometer	B
019	Immunoelectrophoresis equipment	Peralatan imunoelektroforesis	B
020	Automated indirect immunofluorescence microscope and software-assisted system	Mikroskop imunofluoresensi otomatis dan sistem <i>software</i> penunjang	A

### 03. Peralatan Imunologi dan Mikrobiologi

#### 05. Sistem Tes Imunologikal

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas
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			Risiko
001	Albumin immunological test system	Alat uji imunologi albumin	B
002	Antimitochondrial antibody immunological test system	Alat uji imunologi antibodi antimitokondria (contoh: HbsAg, HBV)	D
003	Antinuclear antibody immunological test system	Alat uji imunologi antibodi antinuklear (contoh: HCV kontrol/kalibrator)	B
004	Antiparietal antibody immunological test system	Alat uji imunologi antibodi antiparietal	B
005	Antismooth muscle antibody immunological test system	Alat uji imunologi antibodi otot <i>antismooth</i>	B
006	Alpha -1-antitrypsin immunological test system	Alat uji imunologi <i>alpha -1-antitrypsin</i> .	B
007	Bence-Jones proteins immunological test system	Alat uji imunologi protein <i>Bence-Jones</i> .	B
008	Fecal calprotectin immunological test system	Alat uji imunologi <i>calprotectin</i> feses.	B
009	Ceruloplasmin immunological test system	Alat uji imunologi <i>seruloplasmin</i> .	B
010	Complement components immunological test system	Alat uji imunologi komplemen komponen	B
011	Complement C[bdi2] inhibitor (inactivator) immunological test system	Alat uji imunologi komplemen inhibitor (inaktivator) C [bdi2]	B
012	Complement C 3b inactivator immunological test system	Alat uji imunologis komplemen inaktivator C 3b	B
013	C-reactive protein immunological test system	Alat uji imunologi protein C-reaktif.	B
014	Properdin factor B immunological test system	Alat uji imunologi faktor B <i>properdin</i>	B
015	Ferritin immunological test system	Alat uji imunologi <i>ferritin</i>	B
016	Fibrinopeptide A immunological test system	Alat uji imunologi <i>fibrinopeptida A</i>	B

017	Free secretory component immunological test system	Alat uji imunologi komponen sekretori bebas.	B
018	Haptoglobin immunological test system	Alat uji imunologi haptoglobin.	B
019	Hemoglobin immunological test system	Alat uji imunologi hemoglobin.	B
020	Hemopexin immunological test system	Alat uji imunologi hemopeksin.	B
021	Hypersensitivity pneumonitis immunological test system	Alat uji imunologi hipersensitivitas pneumonitis	B
022	Immunoglobulins A, G, M, D, and E immunological test system	Alat uji imunologi imunoglobulin A, G, M, D, dan E	B
023	Immunoglobulin (light chain specific) immunological test system	Alat uji imunologi imunoglobulin ( <i>light chain specific</i> )	B
024	Alpha -1-lipoprotein immunological test system.	Alat uji imunologi alfa -1-lipoprotein.	B
025	Low-density lipoprotein immunological test system	Alat uji imunologis lipoprotein densitas rendah	B
026	Alpha -2-macroglobulin immunological test system	Alat uji imunologi alfa -2-makroglobulin	B
027	Beta -2-microglobulin immunological test system	Alat uji imunologi beta -2-mikroglobulin	B
028	Infectious mononucleosis immunological test system	Alat uji infeksi mononukleosis	B
029	Myoglobin immunological test system	Alat uji imunologi mioglobin.	B
030	Radioallergosorbent (RAST) immunological test system	Alat uji imunologi <i>Radioallergosorbent (RAST)</i>	B
031	Rheumatoid factor immunological test system	Alat uji <i>Rheumatoid Factor (RF)</i>	B
032	Anti- <i>Saccharomyces cerevisiae</i> (S. <i>cerevisiae</i> ) antibody (ASCA) test systems	Alat uji antibodi <i>Anti-Saccharomyces cerevisiae (S. cerevisiae)</i>	B

033	Systemic lupus erythematosus immunological test system	Alat uji imunologi lupus <i>erythematosus</i> sistemik	B
034	Thyroid autoantibody immunological test system	Alat uji imunologi autoantibodi tiroid.	B
035	Transferrin immunological test system	Alat uji imunologi transferin	B
036	Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system	Alat uji mutasi gen (CFTR)	B
037	Quality control material for cystic fibrosis nucleic acid assays	Kontrol kualitas uji asam nukleat fibrosis kistik.	B
038	Multiple autoantibodies immunological test system	Alat uji imunologi multi autoantibodi (Contoh: HIV kontrol/kalibrator))	B
039	Antimitochondrial antibody immunological test system	Alat uji imunologi antibodi antimitokondria (Contoh: HbsAg kontrol/kalibrator, HBV kontrol/kalibrator)	B
040	Multiparameter immunological test system	Alat uji imunologi multiparameter	C
041	Human leucocyte antibody	Alat uji antibodi leukosit manusia	B
042	Human leucocyte antigen test system	Alat uji HLA, antigen leukosit manusia	B
043	Immunological quality control	Kontrol untuk imunologi	B
044	Automated Bloodborne Pathogen test system	Alat uji patogen melalui darah (Bloodborne Pathogen/BBP) secara otomatis	A
045	Htlv-1 Antibody Immunological test System	Alat uji imunologi antibodi Htlv-1	C
046	Prealbumin immunological test system	Alat uji imunologi prealbumin	B
047	Human allotypic marker immunological test system.	Alat uji imunologi penanda <i>allotypic</i> pada manusia	B

048	Alpha -1-antichymotrypsin immunological test system	Alat uji imunologi <i>alpha -1-antichymotrypsin</i>	A
049	Beta -globulin immunological test system	Alat uji imunologi beta-globulin	B
050	Breast milk immunological test system	Alat uji imunologi ASI	B
051	Carbonic anhydrase B and C immunological test system	Alat uji imunologi <i>anhydrase carbonic B dan C</i>	B
052	Cohn fraction II immunological test system	Alat uji imunologi <i>Cohn fraction II</i>	B
053	Colostrum immunological test system	Alat uji imunologi <i>colostrum</i>	B
054	Factor XIII, A, S, immunological test system	Alat uji imunologi faktor XIII, A, S	B
055	Cohn fraction IV immunological test system	Alat uji imunologi <i>Cohn fraction IV</i>	B
056	Cohn fraction V immunological test system	Alat uji imunologi <i>Cohn fraction V</i>	B
057	Alpha -globulin immunological test system	Alat uji imunologi <i>alpha-globulin</i>	B
058	Alpha -1-glycoproteins immunological test system	Alat uji imunologi <i>alpha -1-glycoproteins</i>	B
059	Alpha -2-glycoproteins immunological test system	Alat uji imunologi <i>alpha -2-glycoproteins</i>	B
060	Beta -2-glycoprotein I immunological test system	Alat uji imunologi <i>beta -2-glycoprotein I</i>	B
061	Beta -2-glycoprotein III immunological test system	Alat uji imunologi <i>beta -2-glycoprotein III</i>	B
062	Immunoglobulin G (Fab fragment specific) immunological test system	Alat uji imunologi imunoglobulin G ( <i>Fab Fragment</i> )	B
063	Immunoglobulin G (Fc fragment specific) immunological test system	Alat uji imunologi imunoglobulin G ( <i>Fc Fragment</i> )	B
064	Immunoglobulin G (Fd fragment specific) immunological test	Alat uji imunologi imunoglobulin G ( <i>Fd Fragment</i> )	B

	system		
065	Lactic dehydrogenase immunological test system	Alat uji imunologi <i>dehydrogenase</i> laktat	B
066	Lactoferrin immunological test system	Alat uji imunologi laktoferin	B
067	Lipoprotein X immunological test system	Alat uji imunologi lipoprotein X	B
068	Whole human plasma or serum immunological test system	Alat uji imunologi plasma atau serum manusia	B
069	Plasminogen immunological test system	Alat uji imunologi plasminogen	B
070	Prothrombin immunological test system	Alat uji imunologi protrombin	B
071	Retinol-binding protein immunological test system	Alat uji imunologi protein <i>retinol-binding</i>	B
072	Seminal fluid (sperm) immunological test system	Alat uji imunologi cairan sperma	B
073	Total spinal fluid immunological test system	Alat uji imunologi cairan spinal total	B
074	Inter- alpha trypsin inhibitor immunological test system.	Alat uji imunologi <i>Inter- alpha trypsin inhibitor</i>	B
075	Antinuclear antibody immunological test system.	Alat uji imunologi antibodi antinuklear (Contoh: HCV)	D
076	Aquaporin-4 autoantibody immunological test system	Alat uji imunologi <i>Aquaporin-4 autoantibody</i>	B
077	Multiple autoantibodies immunological test system	Alat uji imunologi multi autoantibodies (Contoh: HIV Viral Load)	C
078	Multiple autoantibodies immunological test system	Alat uji imunologi multi autoantibodies (Contoh: HIV)	D
079	Antimitochondrial antibody immunological test system.	Alat uji imunologi antibodi antimitokondria (Contoh: HbsAg Viral Load, HBV Viral Load)	C



080	Chronic Lymphocytic Leukemia Fish Probe Kit	Alat uji <i>chronic lymphocytic leukemia</i> (CLL)	B
081	Antinuclear antibody immunological test system.	Alat uji imunologi antibodi antinuklear (Contoh: HCV Viral Load)	C
082	Autosomal recessive carrier screening gene mutation detection system.	Alat penapisan mutasi gen resesif autosom	B
083	Genetic health risk assessment system	Alat uji risiko kesehatan genetik	B
084	Newborn screening test for severe combined immunodeficiency disorder (SCID)	Alat penapisan bayi baru lahir untuk SCID	B
085	Tryptase test system	Alat uji <i>tryptase</i>	B
086	Zinc transporter 8 autoantibody immunological test system	Alat uji imunologi autoantibodi <i>zinc transporter 8</i>	B

### 03. Peralatan Imunologi dan Mikrobiologi

#### 06. Sistem Tes Imunologikal Antigen Tumor

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Tumor-associated antigen immunological test system	Alat uji imunologi antigen terkait tumor.	C
002	Immunomagnetic circulating cancer cell selection and enumeration system	Alat uji <i>immunomagnetic circulating</i> sel kanker dan enumerasi	B
003	AFP-L3% immunological test system	Alat uji imunologi AFP-L3%	C
004	Gene expression profiling test system for breast cancer prognosis	Alat uji ekspresi gen pada prognosis kanker payudara	B
005	Mutation detection test for myeloproliferative neoplasms	Alat uji mutasi <i>myeloproliferative neoplasma</i>	B
006	Cancer 549 Antigen Immunological Test System	Alat uji imunologi CA 549 ( <i>Cancer antigen 549</i> )	C

007	Soluble Mesothelin- Related Peptides Test System	Alat uji <i>mesothelin</i> terlarut - <i>related peptides</i>	C
008	Ovarian Adnexal Mass Assessment Score Test System	Alat uji nilai massa adneksa ovarian (ovarium)	B
009	Complexed Prostate Specific Antigen (CPSA) Immunological Test System	Alat uji imunologi CPSA (Complexed Prostate Specific Antigen)	C
010	Bcr/Ab11 Immunological Test System	Alat uji imunologi Bcr/ Ab11	B
011	BRAF gene mutation test system	Alat uji mutasi gen BRAF	B
012	Her2/Neu Gene Nucleic Acid Amplification for Breast Cancer using Chromogenic In Situ Hybridisation	Alat uji <i>Her2/Neu Amplification</i> gen asam nukleat untuk kanker payudara menggunakan <i>chromagenic in situ hybridisation</i>	C
013	DNA Detection for Human Papillomavirus	Alat uji DNA <i>Papillomavirus</i> (HPV)	C
014	Colorectal Neoplasia, DNA Methylation and Hemoglobin Detection test system	Alat uji deteksi <i>colorectal neoplasia</i> , <i>DNA methylation</i> dan hemoglobin	B
015	Next Generation Sequencing Oncology Panel, Somatic Or Germline Variant Detection System	Alat uji panel sekuensing onkologi, somatik atau variasi <i>germline</i>	B
016	BCR-ABL quantitation test	Alat uji imunologi BCR – ABL	B

#### 04. Peralatan Anestesi

##### 01. Peralatan Anestesi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Manual algesimeter	Algometer/algesiometer manual	A
002	Powered algesimeter	Algometer/algesiometer elektrik	B
003	Argon gas analyzer	Alat pengukur gas argon	C
004	Arterial blood sampling kit	Kit pengambilan sampel darah	B

		arteri	
005	Indwelling blood oxyhemoglobin concentration analyzer	Alat pengukur konsentrasi oksihemoglobin darah, <i>indwelling</i>	D
006	Indwelling blood carbon dioxide partial pressure (P CO <sub>2</sub> ) analyzer.	Alat pengukur tekanan karbon dioksida darah parsial (P CO <sub>2</sub> ), <i>indwelling</i>	C
007	Indwelling blood hydrogen ion concentration (pH) analyzer	Alat pengukur konsentrasi ion hidrogen darah (pH), <i>indwelling</i>	C
008	Indwelling blood oxygen partial pressure (P O <sub>2</sub> ) analyzer	Alat pengukur tekanan parsial oksigen darah (P O <sub>2</sub> ), <i>indwelling</i>	C
009	Carbon dioxide gas analyzer	Alat pengukur gas karbon dioksida	C
010	Carbon monoxide gas analyzer.	Alat pengukur gas karbon monoksida	C
011	Enflurane gas analyzer	Alat pengukur gas enfluran	C
012	Halothane gas analyzer	Alat pengukur gas halotan	C
013	Helium gas analyzer	Alat pengukur gas helium	C
014	Neon gas analyzer	Alat pengukur gas neon	C
015	Nitrogen gas analyzer	Alat pengukur gas nitrogen	C
016	Nitrous oxide gas analyzer	Alat pengukur gas dinitrogen oksida	C
017	Oxygen gas analyzer	Alat pengukur gas oksigen	C
018	Oxygen uptake computer	Alat hitung jumlah oksigen	B
019	Pressure plethysmograph	<i>Whole body plethysmograph</i> (WBP) tekanan	B
020	Volume plethysmograph	<i>Whole body plethysmograph</i> (WBP) volume	B
021	Inspiratory airway pressure meter	Alat pengukur tekanan inspirasi	B
022	Rhinoanemometer	<i>Rhinoanemometer</i>	B
023	Diagnostic spirometer	Spirometer diagnostik	B
024	Monitoring spirometer	Spirometer pemantauan	B
025	Peak-flow meter for spirometry	<i>Peak-flow meter</i> (PFM)	B

026	Pulmonary-function data calculator	Alat hitung data fungsi paru	B
027	Predictive pulmonary-function value calculator	Alat hitung nilai fungsi paru prediktif	B
028	Diagnostic pulmonary-function interpretation calculator	Alat hitung interpretasi fungsi paru diagnostik	B
029	Esophageal stethoscope with electrical conductors.	Stetoskop esofagus dengan konduktor elektrik	B
030	Stethoscope head.	Kepala stetoskop	A
031	Switching valve (ploss).	Katup pengalih (ploss)	A
032	Gas collection vessel.	Wadah pengumpul gas	B
033	Gas volume calibrator.	Kalibrator volume gas.	B
034	Esophageal stethoscope.	Stetoskop esofagus.	B
035	Water vapor analyzer.	Alat analisa uap air.	B
036	COVID-19 detecting breathing device	Alat pendeteksi COVID-19 melalui pernafasan	B
037	Ventilatory electrical impedance tomography	Tomografi impedansi listrik ventilatori	C

#### 04. Peralatan Anestesi

##### 02. Peralatan Anestesi Pemantauan

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Ultrasonic air embolism monitor	Monitor emboli udara ultrasonik	C
002	Breathing frequency monitor	Monitor frekuensi pernapasan	B
003	Apnea monitor	Monitor apnea	B
004	Nitric oxide analyzer	Alat analisa oksida nitrat	C
005	Nitrogen dioxide analyzer	Alat analisa nitrogen dioksida	C
006	Lung water monitor	Monitor cairan paru-paru	D

007	Cutaneous carbon dioxide (PcCO <sub>2</sub> ) monitor	Monitor karbon dioksida kulit (PcCO <sub>2</sub> )	C
008	Cutaneous oxygen (PcO <sub>2</sub> ) monitor	Monitor oksigen kulit (PcO <sub>2</sub> )	C
009	Pneumotachometer	<i>Pneumotachometer</i>	B
010	Airway pressure monitor	Monitor tekanan udara	C
011	Electrical peripheral nerve stimulator	Stimulator saraf perifer listrik	B
012	Bourdon gauge flowmeter	Flowmeter <i>bourdon gauge</i>	A
013	Uncompensated thorpe tube flowmeter	Flowmeter tabung thorpe tidak terkompensasi	A
014	Compensated thorpe tube flowmeter	Flowmeter tabung thorpe terkompensasi	A
015	Gas calibration flowmeter	Alat kalibrasi flowmeter	A
016	Gas pressure gauge	Alat pembaca tekanan gas	A
017	Gas pressure calibrator	Kalibrator tekanan gas	A
018	Pressure regulator	Regulator gas medis	A
019	Differential pressure transducer	Transduser pembagi tekanan gas	A
020	Gas flow transducer	Transduser aliran gas	A
021	Gas pressure transducer	Transduser tekanan gas	A

#### 04. Peralatan Anestesi

##### 03. Peralatan Anestesi Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Emergency airway needle	Jarum jalan napas darurat	B
002	Device to relieve acute upper airway obstruction	Alat untuk meringankan obstruksi jalan nafas atas akut	B
003	Anesthesia conduction catheter	Kateter konduksi anestesi	B
004	Anesthesia conduction filter	Filter konduksi anestesi	B
005	Anesthesia conduction kit	Kit konduksi anestesi	C
006	Anesthesia conduction needle	Jarum konduksi anestesi	B

007	Gas machine for anesthesia or analgesia	<i>Anaesthetic machine</i> , mesin anestesi, Anestesi unit	C
008	Nitric oxide administration apparatus	<i>Nitric oxide concentration</i>	C
009	Laryngotracheal topical anesthesia applicator	<i>Topical anesthetics to a patient's laryngotracheal area</i>	B
010	Rocking bed	Tempat tidur bergerak untuk membantu pasien bernafas	C
011	Blow bottle	Botol tiup	A
012	Anesthesia breathing circuit	Sirkuit pernapasan untuk anestesi	A
013	Breathing circuit circulator	Alat sirkulasi untuk sirkuit pernapasan	B
014	Breathing circuit bacterial filter	Filter bakteri untuk sirkuit pernafasan	B
015	Breathing system heater	Pemanas untuk sistem pernapasan	B
016	Breathing tube support	Alat pendukung selang pernapasan	A
017	Breathing gas mixer	Pencampur gas, mikser gas	B
018	Nasal oxygen cannula	Kanula oksigen untuk hidung / nasal	A
019	Posture chair for cardiac or pulmonary treatment	Kursi postur untuk perawatan jantung atau paru	A
020	Heat and moisture condenser (artificial nose)	Kondensor panas dan kelembaban (hidung buatan)	A
021	Electroanesthesia apparatus	Alat elektroanestesi	D
022	Ether hook	Pengait eter	A
023	Gas-scavenging apparatus	Sistem pembuangan gas anestesi, AGSS	B
024	Portable oxygen generator	Generator oksigen portabel	B
025	Respiratory gas humidifier	<i>Humidifier</i> gas pernapasan	B
026	Hyperbaric chamber	Ruang hiperbarik	C
027	Anesthetic gas mask	Masker gas anestesi	A
028	Gas mask head strap	Pengikat kepala masker gas	A
029	Nonbreathing mask	Masker <i>nonbreathing</i>	A

030	Oxygen mask	Masker oksigen	A
031	Scavenging mask	Masker <i>scavenging</i>	A
032	Venturi mask	Masker <i>venturi</i>	A
033	Breathing mouthpiece	Corong pernapasan, <i>breathing mouthpiece</i>	A
034	Nebulizer	<i>Nebulizer</i>	B
035	Esophageal obturator	Obturator esofagus	B
036	Portable liquid oxygen unit	Unit oksigen cair portabel, tabung oksigen kosong	B
037	Powered percussor	<i>Percussor</i> elektrik / tekanan gas	B
038	Rebreathing device	Perangkat <i>rebreathing</i>	A
039	Incentive spirometer	Spirometer insentif	B
040	Electrically powered oxygen tent	Tenda oksigen bertenaga listrik	B
041	Bronchial tube	Selang bronkus	B
042	Tracheal tube	Selang trakea	B
043	Tracheal/bronchial differential ventilation tube	Selang ventilasi diferensial trakea / bronkus	B
044	Inflatable tracheal tube cuff	Selang manset trakea	B
045	Cuff spreader	<i>Spreader</i> manset	A
046	Tracheal tube fixation device	Perangkat fiksasi selang trakea	A
047	Tube introduction forceps	Tang pengantar selang	A
048	Tracheal tube cleaning brush	Sikat pembersih selang trakea	A
049	Tracheostomy tube and tube cuff	Selang trakeostomi dan manset selang	B
050	Airway connector	Konektor saluran udara	A
051	Dental protector	Pelindung gigi	A
052	Autotransfusion apparatus	Peralatan autotransfusi	B
053	Nonrebreathing valve	Katup <i>non-rebreathing</i>	B
054	Anesthetic vaporizer	Vapor anestesi	C
055	Continuous ventilator	Ventilator kontinu, <i>invasive ventilator</i> , ventilator ICU	C
056	Noncontinuous ventilator (IPPB)	Ventilator non-kontinu (IPPB), <i>non invasive ventilator</i>	C
057	Manual emergency ventilator	Ventilator darurat manual	B

058	Powered emergency ventilator	Ventilator darurat elektrik / tekanan	C
059	External negative pressure ventilator	Ventilator tekanan negatif eksternal	C
060	Intermittent mandatory ventilation attachment	Alat penghubung ventilator (IMV)	B
061	Positive end expiratory pressure breathing attachment	Alat penghubung tekanan positif dan ekspirasi pernafasan.	B
062	Tee drain (water trap)	<i>Tee drain</i> (perangkap air)	A
063	Combined spinal/epidural anesthesia	Anestesi kombinasi tulang belakang / epidural	C
064	Oxygen Generator System	Sistem generator oksigen	B
065	Skin Refrigerant	Pendingin kulit	B
066	Nasopharyngeal airway	Saluran udara nasofaring	A
067	Oropharyngeal airway	Saluran udara orofaring	A
068	Carbon dioxide absorbent	Absorben CO <sub>2</sub>	B
069	Carbon dioxide absorber	Alat penyerap CO <sub>2</sub>	B
070	Reservoir bag	Kantong reservoir	B
071	Nasal oxygen catheter	Kateter oksigen untuk hidung / nasal	B
072	Therapeutic humidifier for home use	Terapi <i>humidifier</i> untuk penggunaan di rumah	B
073	Flexible laryngoscope	Laringoskop fleksibel	B
074	Rigid laryngoscope	Laringoskop kaku	A
075	Medicinal nonventilatory nebulizer (atomizer)	<i>Nebulizer</i> obat non-ventilatori ( <i>atomizer</i> )	B
076	Nonpowered oxygen tent	Tenda oksigen non-elektrik / tekanan	B
077	Tracheal tube stylet	<i>Stylet</i> selang trakea	B
078	Pressure tubing and accessories	Selang dan aksesoris untuk gas bertekanan	A
079	Ventilator tubing	Selang ventilator	A
080	Endobronchial Valve	Katup endobronkial	D



081	High flow humidified oxygen delivery device.	Alat penghantar oksigen terhumidifikasi beraliran tinggi	B
082	Positive airway pressure delivery system	Sistem penghantar saluran udara bertekanan positif	C
083	External negative pressure airway aid	Alat bantu eksternal saluran udara bertekanan negatif	C

#### 04. Peralatan Anestesi

##### 04. Peralatan Anestesi Lainnya

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Portable air compressor	Kompresor udara portabel	B
002	Anesthesia stool	Bangku anestesi	A
003	Patient position support	Pengatur posisi pasien	A
004	Tracheobronchial Suction Catheter	Kateter penghisap <i>tracheobronchial</i>	B
005	Anesthetic cabinet, table, or tray	Troli, kabinet, meja anestesi	A
006	Cardiopulmonary emergency cart	Troli darurat kardiopulmonari	A
007	Nose clip	Klip hidung	A
008	Calibration gas	Gas kalibrasi	A
009	Medical gas yoke assembly	Konektor yoke gas medis	A

#### 05. Peralatan Kardiologi

##### 01. Peralatan Kardiologi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Detektor dan alarm aritmia	C
002	Blood pressure alarm	Alarm tekanan darah	B
003	Blood pressure computer	Komputer pengukur tekanan darah	B
004	Blood pressure cuff	Manset tensimeter	B

005	Noninvasive blood pressure measurement system	Tensimeter, <i>sphygmomanometer</i>	B
006	Venous blood pressure manometer	Manometer tekanan darah vena	B
007	Diagnostic intravascular catheter	Kateter diagnostik intravaskular	C
008	Continuous flush catheter	Kateter pembilas kontinu	C
009	Electrode recording catheter or electrode recording probe	Kateter atau probe elektroda perekam	C
010	Fiberoptic oximeter catheter	Kateter serat optik oksimeter	C
011	Flow-directed catheter	Kateter pengarah aliran	C
012	Intracavitary phonocatheter system	Sistem fonokateter intrakavitari	C
013	Steerable catheter	Kateter yang dapat dikendalikan	C
014	Steerable catheter control system	Sistem pengendali kateter	C
015	Catheter cannula	Kanula kateter	B
016	Vessel dilator for percutaneous catheterization	Bejana dilator untuk kateterisasi	B
017	Catheter guide wire	Kateter <i>guide wire</i>	C
018	Catheter introducer	Kateter <i>introducer</i>	B
019	Catheter balloon repair kit	Kit perbaikan balon kateter	D
020	Trace microsphere	<i>Trace microsphere.</i>	D
021	Catheter tip occluder	Ujung kateter <i>occluder</i>	B
022	Catheter stylet	<i>Stylet</i> kateter	B
023	Trocar	<i>Trocar</i>	B
024	Programmable diagnostic computer	Komputer diagnostik terprogram	B
025	Single-function, preprogrammed diagnostic computer	Komputer diagnostik fungsi-tunggal dan terprogram.	B
026	Densitometer	Densitometer	B
027	Angiographic injector and syringe	Alat suntik / spuit dan injektor angiografi	B
028	Indicator injector	Indikator injektor	B

029	Syringe actuator for an injector	Alat suntik / spuit aktuator untuk injektor	B
030	Withdrawal-infusion pump	Penarik pompa infus	B
031	Stethoscope	Stetoskop	A
032	Fiberoptic Oximetry Catheter	Kateter oksimetri serat optik	C
033	Cardiac support mesh wrap	<i>Cardiac support mesh wrap</i>	D
034	Cardioplegia solution administration kit	Kit pemberian larutan kardioplegia	B
035	Pressure monitoring cardiac catheter	Kateter pemantauan tekanan jantung	C
036	Intracardiac mapping high-density array catheter	Kateter pemetaan <i>intracardiac array</i> kepadatan tinggi	C
037	Closed-loop blood-pressure controller,	Pengendali tekanan darah dengan loop tertutup	D
038	Percutaneous catheter	Kateter perkutan	C
039	External programmable pacemaker pulse generator	Generator pulsa <i>pacemaker</i> / pacu jantung eksternal yang dapat diprogram	B
040	Thermodilution probe	<i>Probe</i> termodilusi	C
041	Electronic stethoscope	Stetoskop elektrik	B
042	Balloon aortic valvuloplasty catheter.	Balon kateter katup aorta	C
043	Coronary vascular physiologic simulation software device.	Perangkat lunak untuk simulasi fisiologis vaskular koroner	C

## 05. Peralatan Kardiologi

### 02. Peralatan Kardiologi Pemantauan

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Biopotential amplifier and signal conditioner.	Penguat biopotensial dan pengkondisi sinyal	B
002	Transducer signal amplifier and	Penguat sinyal transducer	B

	conditioner.	dan kondisioner.	
003	Cardiovascular blood flowmeter.	<i>Flowmeter</i> darah untuk kardiovaskular.	B
004	Extravascular blood flow probe.	<i>Probe</i> pemeriksaan aliran darah ekstrasvaskular	B
005	Cardiac monitor (including cardiometer and rate alarm).	Pasien monitor	B
006	Apex cardiograph (vibrocardiograph).	<i>Apex cardiograph (vibrocardiograph)</i> .	B
007	Ballistocardiograph.	Balistokardiograf	B
008	Echocardiograph.	<i>Echo</i> kardiograf	B
009	Electrocardiograph.	EKG, ECG	B
010	Electrocardiograph lead switching adaptor.	Adaptor <i>switching</i> EKG	B
011	Electrocardiograph electrode.	Elektroda EKG	B
012	Electrocardiograph surface electrode tester.	Penguji permukaan elektrokardiograf	B
013	Vectorcardiograph.	Vektorkardiograf	B
014	Medical cathode-ray tube display.	Penampil hasil medis dengan CRT	B
015	Signal isolation system.	Sistem sinyal isolasi	A
016	Line isolation monitor.	Monitor batas isolasi	A
017	Oscillometer.	Oscillometer	B
018	Oximeter.	Oksimeter	B
019	Ear oximeter.	Oksimeter telinga	B
020	Impedance phlebograph.	<i>Phlebograph</i> impedansi	B
021	Impedance plethysmograph.	<i>Plethysmograph</i> impedansi	B
022	Hydraulic, pneumatic, or photoelectric plethysmographs.	<i>Plethysmographs</i> hidrolik, pneumatik, atau fotoelektrik.	B
023	Medical magnetic tape recorder.	Perekam magnetik medis.	B
024	Paper chart recorder.	Kertas perekam grafik, kertas EKG	A
025	Apex cardiographic transducer.	Transduser apex kardiografik	B

026	Extravascular blood pressure transducer.	Transduser tekanan darah ekstravaskular.	B
027	Heart sound transducer.	Transduser suara jantung.	B
028	Catheter tip pressure transducer.	Kateter tip bertekanan	B
029	Ultrasonic transducer.	Transduser ultrasonik	B
030	Patient transducer and electrode cable (including connector).	Transduser dan kabel elektroda pasien (termasuk konektor).	B
031	Radiofrequency physiological signal transmitter and receiver.	Pemancar dan penerima sinyal fisiologis radio frekuensi	B
032	Telephone electrocardiograph transmitter and receiver.	Pemancar dan penerima elektrokardiograf	B
033	Phonocardiograph.	Fonokardiograf	B
034	Portable leakage current alarm.	Alarm kebocoran arus portabel.	B
035	Implantable Intra-aneurysm Pressure Measurement System	Sistem pengukuran tekanan intraaneurisma yang diimplan.	D
036	Vessel occlusion transducer.	Transduser oklusi pembuluh darah	B
037	Electrocardiograph software for over-the-counter use	Perangkat lunak elektrokardiograf untuk OTC	B
038	Adjunctive cardiovascular status indicator	Indikator status kardiovaskular tambahan	C

## 05. Peralatan Kardiologi

### 03. Peralatan Kardiologi Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Intra-aortic balloon and control system	Balon intra-aorta dan sistem kontrol	D
002	Ventricular bypass (assist) device.	Alat bantu <i>bypass</i> ventrikular.	D
003	External pacemaker pulse	Generator pacu jantung	D

	generator.	eksternal	
004	Implantable pacemaker pulse generator.	Generator pacu jantung implan.	D
005	Pacemaker generator function analyzer.	Alat analisis fungsi generator pacu jantung	B
006	Indirect pacemaker generator function analyzer.	Alat analisis fungsi generator pacu jantung tidak langsung	B
007	Pacemaker programmers.	Pemrogram pacu jantung	D
008	Pacemaker repair or replacement material.	Bahan perbaikan atau penggantian pacu jantung	D
009	Pacemaker electrode function tester.	Penguji fungsi elektroda pacu jantung	B
010	Pacemaker service tools.	Alat perbaikan pacu jantung	A
011	Carotid sinus nerve stimulator.	Stimulator saraf sinus karotis.	D
012	Replacement heart valve.	Katup jantung pengganti	D
013	Coronary stent	<i>Stent</i> coroner	D
014	Drug eluting stent	<i>Stent</i> bersalut obat	D
015	Vascular embolization device	Peralatan embolisasi vaskular	D
016	Automatic Implantable Cardioverter Defibrillator With Cardiac Resynchronization (Crt-D)	<i>Defibrillator cardioverter</i> implan otomatis dengan resinkronisasi jantung (Crt-D)	D
017	Cardiac occluder	<i>Occluder</i> kardiak	D
018	Cardiology Clip	Klip kardiologi	D
019	Endovascular Suturing System	Sistem penjahitan endovaskular	C
020	Vascular graft prosthesis	Prostesis graft pembuluh darah (pembuluh darah buatan)	C
021	Prosthesis Percutaneously Delivered Aortic Valve	Katup aorta prostesis, pemberian secara perkutan	D
022	Artificial Heart	Jantung artifisial	D

023	Vascular clip for general use	Penjepit vaskular untuk penggunaan umum	B
024	Vena cava clip.	Penjepit vena <i>cava</i> .	B
025	Cardiovascular intravascular filter.	Filter intravaskular kardiovaskular	D
026	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.	<i>Patch</i> intrakardiak terbuat dari <i>polypropylene</i> , <i>polyethylene terephthalate</i> , atau <i>polytetrafluoroethylene</i>	C
027	Pacemaker lead adaptor.	Adaptor pacu jantung	D
028	Pacemaker polymeric mesh bag.	Pacu jantung <i>polymeric mesh bag</i>	C
029	Pacemaker charger.	Pengisi daya pacu jantung	A
030	Cardiovascular permanent pacemaker electrode.	Elektroda alat pacu jantung permanen	D
031	Cardiovascular temporary pacemaker electrode.	Elektroda alat pacu jantung sementara	B
032	Pacemaker test magnet.	Alat uji magnet pacu jantung	B
033	Annuloplasty ring.	Cincin anuloplasti	C
034	Prosthetic heart valve holder.	Dudukan katup jantung prostesis	A
035	Prosthetic heart valve sizer.	Pengukur katup jantung prostesis	A
036	Percutaneous ventricular restoration	Restorasi ventrikular perkutan	B
037	Superficial Femoral Artery Stent	<i>Superficial femoral artery stent</i>	C
038	Pacing system analyzer.	Sistem analisis alat pacu jantung	C
039	Vascular clip for cardiac use.	Klip vaskular untuk jantung	D

05. Peralatan Kardiologi

04. Peralatan Kardiologi Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Cardiopulmonary bypass bubble detector.	Detektor gelembung <i>bypass</i> kardiopulmonari	C
002	Cardiopulmonary bypass vascular catheter, cannula, or tubing.	Kateter, kanula, atau selang vaskular <i>bypass</i> kardiopulmonari	C
003	Cardiopulmonary bypass heart-lung machine console.	Konsol mesin jantung-paru <i>bypass</i> kardiopulmonari	C
004	Cardiopulmonary bypass defoamer.	Pencegah gelembung gas pada <i>bypass</i> kardiopulmonari	C
005	Cardiopulmonary bypass heat exchanger.	Penukar panas pada <i>bypass</i> kardiopulmonari.	B
006	Cardiopulmonary bypass temperature controller.	Pengontrol suhu pada <i>bypass</i> kardiopulmonari.	B
007	Cardiopulmonary bypass arterial line blood filter.	Filter darah arteri pada <i>bypass</i> kardiopulmonari	C
008	Cardiopulmonary bypass cardiotomy suction line blood filter.	Filter darah cardiotomy pada <i>bypass</i> kardiopulmonari.	C
009	Cardiopulmonary prebypass filter.	Filter pada <i>prebypass</i> kardiopulmonari	C
010	Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.	Adaptor <i>stopcock</i> , <i>manifold</i> , atau <i>fitting</i> pada <i>bypass</i> kardiopulmonari, <i>Y-connector</i>	C
011	Cardiopulmonary bypass gas control unit.	Unit kontrol gas pada <i>bypass</i> kardiopulmonari.	C
012	Cardiopulmonary bypass coronary pressure gauge.	Pengukur tekanan koroner pada <i>bypass</i> kardiopulmonari	C
013	Cardiopulmonary bypass pulsatile flow generator.	Generator aliran <i>pulsatil</i> pada <i>bypass</i> kardiopulmonari	D
014	Cardiopulmonary bypass on-line blood gas monitor.	Monitor gas darah pada <i>bypass</i> kardiopulmonari	B



015	Cardiopulmonary bypass level sensing monitor and/or control.	Monitor dan / atau kontrol level penginderaan pada <i>bypass</i> kardiopulmonari	C
016	Cardiopulmonary bypass oxygenator.	Oksigenator pada <i>bypass</i> kardiopulmonari	C
017	Roller-type cardiopulmonary bypass blood pump.	Pompa darah tipe <i>roller</i> pada <i>bypass</i> kardiopulmonari	B
018	Cardiopulmonary bypass pump speed control.	Kontrol kecepatan pompa pada <i>bypass</i> kardiopulmonari	B
019	Cardiopulmonary bypass pump tubing.	Selang pompa pada <i>bypass</i> kardiopulmonari.	B
020	Cardiopulmonary bypass blood reservoir.	Penampung darah pada <i>bypass</i> kardiopulmonari.	C
021	Cardiopulmonary bypass in-line blood gas sensor.	Sensor gas darah pada <i>bypass</i> kardiopulmonari <i>in-line</i> .	B
022	Cardiopulmonary bypass cardiotomy return sucker.	<i>Cardiopulmonary bypass cardiotomy return sucker</i> .	C
023	Cardiopulmonary bypass intracardiac suction control.	Kontrol hisap intrakardiak pada <i>bypass</i> kardiopulmonari	C
024	Vascular clamp.	Penjepit pembuluh darah.	B
025	Surgical vessel dilator.	Dilator pembuluh darah pada pembedahan.	B
026	Cardiovascular surgical instruments.	Instrumen bedah kardiovaskular	A
027	Intraluminal artery stripper.	<i>Stripper</i> arteri intraluminal.	B
028	External vein stripper.	<i>Stripper</i> vena eksternal.	B
029	Cardiopulmonary bypass adaptor	Adaptor pada <i>bypass</i> kardiopulmonari	C
030	Cardiac ablation percutaneous catheter	Kateter ablasi kardiak perkutan	D
031	Coronary atherectomy catheter	Kateter <i>coronary atherectomy</i>	B

032	Central Venous Catheter Tray (Kit)	Kit kateter vena sentral	C
033	Endomyocardial biopsy device.	Alat biopsi endomiokardial.	D
034	Cardiopulmonary bypass accessory equipment.	Peralatan aksesori pada <i>bypass</i> kardiopulmonari.	C
035	Vascular closure device	Alat penutup vaskular	D
036	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure	Sirkuit ekstrakorporeal dan aksesori untuk kegagalan pernapasan/ kardiopulmonari jangka panjang	C
037	Nonroller-type blood pump ( <i>Nonroller-type cardiopulmonary and circulatory bypass blood pump</i> )	Pompa darah <i>bypass</i> kardiopulmonari dan peredaran darah tipe <i>non-roller</i>	C
038	Nonroller-type blood pump ( <i>Nonroller-type temporary ventricular support blood pump</i> )	Pompa darah pendukung ventrikel sementara tipe <i>non-roller</i>	D
039	Apical closure device.	Alat penutup apikal	C

## 05. Peralatan Kardiologi

### 05. Peralatan Kardiologi Terapetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Patient care suction apparatus.	Alat penghisap cairan yang digunakan bersamaan dengan kateter intra-toraks	B
002	Embolectomy catheter.	Kateter embolektomi	C
003	Septostomy catheter.	Kateter septostomi.	C
004	External counter-pulsating device.	Alat penghitung denyut jantung eksternal.	C
005	DC-defibrillator (including paddles).	Defibrilator-DC (termasuk <i>paddles</i> )	C
006	Automated external defibrillator system	Defibrilator eksternal otomatis.	C
007	Defibrillator tester.	Penguji defibrilator.	B
008	External transcutaneous cardiac pacemaker (noninvasive).	Pacu jantung transkutan eksternal (non-invasif)	C

009	Compressible limb sleeve.	<i>Compressible limb sleeve</i>	B
010	Thermal regulating system.	Sistem pengaturan termal pasien	B
011	Automatic rotating tourniquet	<i>Tourniquet</i> berputar otomatis	B
012	Cardiovascular adhesion barrier	Barier adhesi kardiovaskular	D
013	Implantable dual-chamber defibrillator	<i>Implantable dual-chamber defibrillator</i>	D
014	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.	Kateter PTCA	C
015	External cardiac compressor.	Kompresor jantung eksternal.	C
016	Cutting/scoring Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter	Kateter PTCA untuk <i>cutting / scoring</i>	D
017	Drug Eluting Balloon	Balon bersalut obat	D
018	Vascular Hemostatis Device	Alat hemostatis vaskular	D
019	Peripheral Angioplasty Laser Device	Alat laser <i>angioplasty</i> periferal	C
020	Cardiopulmonary resuscitation (CPR) aid without feedback	CPR tanpa umpan balik	A
021	Cardiopulmonary resuscitation (CPR) aid with feedback	CPR dengan umpan balik	C
022	Steerable cardiac ablation catheter remote control system.	Sistem kateter ablasi jantung dengan kendali jarak jauh	C
023	Esophageal thermal regulation device.	Perangkat pengaturan termal esofagus	C

## 06. Peralatan Gigi

### 01. Peralatan Gigi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Pulp tester.	<i>Pulp tester</i> ; alat uji pulpa gigi	B
002	Electrode gel for pulp testers.	Gel elektroda untuk alat uji	A

		pulpa gigi	
003	Caries detection device.	Alat deteksi karies gigi	B
004	Laser fluorescence caries detection device.	Alat deteksi karies gigi dengan laser fluoresensi	C
005	Extraoral source x-ray system.	Alat rontgen gigi ekstra oral, <i>extra oral dental x-ray system, extraoral radiography, dental x ray unit, dental x-ray panoramic, cephalometric, dental cbct (cone beam computed tomography)</i>	C
006	Intraoral source x-ray system.	Alat rontgen gigi intra oral, sistem sinar x intra oral dental, intra oral radiography	C
007	Dental x-ray exposure alignment device.	Perangkat penyelarasan paparan sinar x gigi, <i>beam alignment device</i>	A
008	Cephalometer.	<i>Cephalometer</i>	B
009	Dental x-ray position indicating device.	<i>Position Indicating Device (PID), cone, tube</i>	A
010	Lead-lined position indicator.	<i>Lead-lined position indicator</i>	A
011	Sulfide detection device.	Alat deteksi sulfida	B
012	Dental x-ray film holder	Pemegang film sinar x gigi, <i>x-ray film position holders</i>	A
013	Root apex locator	<i>Locator akar gigi</i>	B
014	Gingival fluid measurer	Pengukur cairan <i>gingival</i>	A
015	Dental sonography device	<i>Dental sonography, electrosonography</i>	B
016	Jaw tracking device	Alat pengukur pergerakan rahang	B

## 06. Peralatan Gigi

### 02. Peralatan Gigi Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas
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			Risiko
001	Noble metal alloy	Bahan campuran logam mulia untuk pembuatan <i>crown</i> dan <i>bridge</i> gigi	B
002	Preformed anchor	Jangkar gigi tiruan	A
003	Resin applicator	<i>Disposable resin applicators</i> , kuas resin	A
004	Articulator	<i>Dental articulator</i>	A
005	Precision attachment.	<i>Prosthodontics precision attachment</i>	A
006	Resin tooth bonding agent	<i>Dental bonding agents</i>	B
007	Facebow	<i>Dental facebow</i>	A
008	Dental bur	<i>Dental bur</i>	A
009	Calcium hydroxide cavity liner	<i>Calcium hydroxide cavity liner</i>	C
010	Cavity varnish	<i>Cavity varnish</i>	B
011	Dental cement	Semen gigi berbahan <i>Zinc oxide eugenol</i> , <i>temporary dental cement</i>	B
012	Performed Clasp	Klamer, cangkolan, <i>stainless steel wire clasps</i>	A
013	Hydrophilic resin coating for dentures	Pelapis resin hidrofilik untuk gigi tiruan	B
014	Coating material for resin fillings	<i>Varnishes/resin-glazes</i>	B
015	Karaya and sodium borate with or without acacia denture adhesive	Karaya dan natrium borat dengan atau tanpa perekat gigi tiruan akasia <i>denture adhesive</i>	D
016	Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive	<i>Homopolimer etilena oksida</i> dan/atau perekat <i>natrium karboksimetilselulosa/denture adhesive</i>	A
017	Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive	<i>Karboksimetilselulosa natrium</i> dan perekat <i>kationik poliakrilamida kationik/denture adhesive</i>	D

018	Ethylene oxide homopolymer and/or karaya denture adhesive	<i>Homopolimer etilena oksida dan/atau perekat gigi karaya/ denture adhesive</i>	A
019	Polyacrylamide polymer (modified cationic) denture adhesiv	Bahan perekat <i>polimer polyacrylamide</i> (dimodifikasi kationik)/ <i>denture adhesive</i>	D
020	Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive	<i>Carboxymethylselulose sodium dan/atau polyvinylmethylether maleic acid kalsium-sodium double salt</i> gigi tiruan perekat/ <i>denture adhesive</i>	A
021	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive	<i>Anhidrida maleat polivinilmetileter (PVM-MA), kopolimer asam, dan perekat gigi tiruan natriumkarboksimetilselulosa (NACMC)/ denture adhesive</i>	D
022	OTC denture cleanser	Pembersih gigi OTC	A
023	Mechanical denture cleaner	Alat pembersih gigi mekanik	A
024	OTC denture cushion or pad	Bantal denture OTC	B
025	OTC denture reliner	Dentur <i>reliner</i> OTC	B
026	OTC denture repair kit	Kit perbaikan denture OTC	B
027	Preformed gold denture tooth	Dentur <i>preformed</i> emas	A
028	Preformed plastic denture tooth	Dentur <i>preformed</i> plastik	B
029	Partially fabricated denture kit	Kit <i>fabricated</i> dentur	B
030	Endosseous dental implant abutment	Abutment implan gigi	C
031	Endosseous dental implant	Implan gigi	C
032	Subperiosteal implant material	Material implan <i>subperiosteal</i>	C
033	Impression material.	Bahan cetak	B
034	Optical Impression Systems for CAD/CAM	CAD/CAM	B
035	Resin impression tray material	Bahan <i>tray</i> resin	A
036	Polytetrafluoroethylene (PTFE) vitreous carbon materials	Bahan PTFE carbon	C

037	Tooth shade resin material	Bahan resin	B
038	Base metal alloy	Bahan campuran logam basis	B
039	Pantograph	<i>Dental pantograph</i>	A
040	Retentive and splinting pin	Pin/pasak	A
041	Bracket adhesive resin and tooth conditioner	Perekat braket resin komposit ortodonsi	B
042	Denture relining, repairing, or rebasing resin.	<i>Relining, repairing, rebasing</i> dari resin untuk gigi tiruan lepasan	B
043	Pit and fissure sealant and conditioner	<i>Pit and fissure sealant</i>	B
044	Temporary crown and bridge resin	Bahan resin untuk <i>crown</i> dan <i>bridge</i> sementara	B
045	Root canal post	Penstabil akar gigi	A
046	Root canal filling resin (contain chloroform)	Bahan pengisi saluran akar dari resin (mengandung kloroform)	D
047	Endodontic paper point	<i>Paper point, absorbent paper point, paper point</i> pengering saluran akar	A
048	Endodontic silver point	<i>Paper point</i> pengisi saluran akar gigi dari perak	A
049	Endodontic stabilizing splint	<i>Splint</i> penstabil akar gigi (contoh: terbuat dari titanium)	C
050	Porcelain tooth	Gigi palsu dari porselen	B
051	Bone grafting material	<i>Bone graft</i> ; bahan cangkok tulang	C
052	Total temporomandibular joint prosthesis	Prostesis TMJ	D
053	Glenoid fossa prosthesis	Prostesis <i>glenoid fossa</i>	D
054	Mandibular condyle prosthesis	Prostesis <i>mandibular condylar</i>	D
055	Interarticular disc prosthesis (interpositional implant)	Prostesis <i>disc</i> inter-artikular (implan <i>interpositional</i> )	D
056	Endosseous dental implant accessories	Aksesori implan gigi	A

057	Root canal filling resin	Resin pengisi saluran akar	C
058	Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive	Perekat gigi tiruan <i>homopolimer etilen oksida</i> dan/atau natrium CMC	A
059	Preformed crown	Crown gigi siap pakai	A
060	Gold or stainless steel cusp	<i>Cusp</i> terbuat dari emas atau <i>stainless steel</i>	A
061	Preformed cusp	<i>Cusp</i> siap pakai	A
062	Gutta percha	<i>Gutta percha</i>	A
063	Posterior artificial tooth with a metal insert	Gigi artifisial posterior dengan <i>insert</i> logam	B
064	Bone grafting material (contain drug)	<i>Bone graft</i> ; bahan cangkok tulang (mengandung obat)	D
065	Dental cement	Semen gigi (selain zinc dan eugenol)	C

## 06. Peralatan Gigi

### 03. Peralatan Gigi Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Bone cutting instrument and accessories	Instrumen dan aksesoris pemotong tulang rahang	B
002	Gas-powered jet injector	<i>Injector</i> bertekanan gas	B
003	Spring-powered jet injector	<i>Injector</i> pegas	B
004	Dental diamond instrument	Bor gigi intan	A
005	Dental hand instrument	Instrumen gigi	A
006	Intraoral ligature and wire lock	<i>Ligature wire</i>	B
007	Fiber optic dental light	Lampu gigi serat optik	A
008	Dental operating light	Lampu operasi gigi	A
009	Bone plate	Pelat tulang rahang	C
010	Rotary scaler	<i>Scaler</i>	B
011	Ultrasonic scaler	<i>Scaler</i> ultrasonik	B
012	Intraosseous fixation screw or wire	<i>Screw</i> atau kawat fiksasi	C



		intraoseus	
013	Dental electrosurgical unit and accessories.	ESU gigi dan aksesoris	C
014	Dental handpiece and accessories	<i>Handpiece</i> gigi dan aksesoris	B
015	Intraoral dental drill.	<i>Drill</i> gigi intraoral	B
016	Dental injecting needle.	Jarum injeksi gigi	B

06. Peralatan Gigi

04. Peralatan Gigi Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Orthodontic appliance and accessories	Kawat gigi dan aksesoris	A
002	Orthodontic plastic bracket	<i>Bracket</i> gigi plastik	B
003	Extraoral orthodontic headgear	<i>Headgear</i> ortodontik	B
004	Preformed tooth positioner	Pengatur posisi gigi siap pakai, <i>retainer</i>	A
005	Teething ring	<i>Teether</i> tidak berisi air	A
006	Intraoral devices for snoring and obstructive sleep apnea.	Alat anti dengkur	B
007	Oral rinse to reduce the adhesion of dental plaque	Cairan untuk mengurangi plak/karang gigi	B
008	Water filled teething ring	<i>Teether</i> berisi air	B
009	Gingival retraction/hemostatic paste	Retraksi gingiva/pasta hemostatik	C

06. Peralatan Gigi

05. Peralatan Gigi Lainnya

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Abrasive device and accessories	Alat abrasif dan aksesoris	A

002	Oral cavity abrasive polishing agent	Bahan pemoles oral, <i>prophylaxis pastes</i>	A
003	Saliva absorber	Penyerap saliva, <i>dental cotton roll</i> ; <i>saliva absorber pad</i>	A
004	Ultraviolet activator for polymerization	<i>Dental curing UV light</i> ; <i>UV light curing unit</i> ; <i>curing UV light polymerization unit</i>	B
005	Airbrush	<i>Airbrush</i>	B
006	Anesthetic warmer	Penghangat obat anestesi	A
007	Articulation paper	<i>Articulating paper</i>	A
008	Base plate shellac	Pelat dasar cetak gigi terbuat dari <i>shellac</i>	A
009	Prophylaxis cup	<i>Prophylaxis cup</i>	A
010	Rubber dam and accessories	<i>Rubber dam</i> dan aksesoris	A
011	Ultraviolet detector	Detektor ultraviolet	B
012	Dental floss	Benang gigi	A
013	Impression tube	Tabung impresi, <i>copper tube</i>	A
014	Massaging pick or tip for oral hygiene	Tusuk gigi, <i>gum massager</i> ; <i>gum stimulator</i> ; <i>rubber tip stimulator</i>	A
015	Porcelain powder for clinical use	Serbuk porselen gigi	B
016	Silicate protector	Protector silikat	A
017	Endodontic dry heat sterilizer	Sterilizer panas kering endodontik	C
018	Cartridge syringe	<i>Dental cartridge syringe</i>	B
019	Manual toothbrush	Sikat gigi manual	A
020	Disposable flouride tray	<i>Tray flouride</i> sekali pakai	A
021	Preformed impression tray	Cetakan gigi siap pakai	A
022	Intraoral dental wax	<i>Dental wax</i> ; lilin <i>dental</i>	A
023	Dental chair and accessories	Kursi gigi dan aksesoris	A
024	Heat source for bleaching teeth	Alat pemutih gigi dengan sumber panas	B
025	Oral irrigation unit	Unit irigasi oral	B
026	Dental operative unit and	<i>Dental unit</i> ; <i>dental system</i>	A

	accessories		
027	Boiling water sterilizer	Sterilisator air panas	B
028	Powered toothbrush	Sikat gigi elektrik	B
029	Artificial saliva	Saliva buatan	B

07. Peralatan Telinga, Hidung, dan Tenggorokan

01. Peralatan THT Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Audiometer	Audiometer	B
002	Acoustic chamber for audiometric testing	<i>Chamber</i> audiometri	A
003	Auditory impedance tester	Timpanometer	B
004	Earphone cushion for audiometric testing	<i>Headset</i> audiometri, <i>headphone</i> audiometer, <i>audiometric headphone</i>	A
005	Electronic noise generator for audiometric testing	Penghasil kebisingan untuk tes audiometri	B
006	Electroglottograph	Pengukur getaran pita suara	B
007	Olfactory test device	<i>Odor test device</i> / alat uji penciuman	B
008	Surgical nerve stimulator/locator	Alat untuk menemukan dan mengidentifikasi saraf	B
009	Toynbee diagnostic tube	Tabung diagnostik <i>toynbee</i>	A
010	Short increment sensitivity index (SISI) adapter	Adapter SISI (digunakan bersama audiometer)	B
011	Audiometer calibration set	Kalibrator audiometer	A
012	Gustometer	<i>Gustometer</i>	B
013	Air or water caloric stimulator	Stimulator vestibular (untuk menguji keseimbangan tubuh)	A

07. Peralatan Telinga, Hidung, dan Tenggorokan

02. Peralatan THT Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
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001	Hearing Aid (Behind The Ear / BTE / Air Conduction)	Alat bantu dengar ( <i>Behind The Ear / BTE / Air Conduction</i> )	A
002	Hearing aid calibrator and analysis system	Kalibrator alat bantu dengar	B
003	Group hearing aid or group auditory trainer	Kelompok alat bantu dengar ( <i>hardwire systems, inductance loop systems, and wireless systems.</i> )	B
004	Master hearing aid	Simulator alat bantu dengar	B
005	Tinnitus masker	Masker <i>tinnitus</i> , masker telinga berdengung	B
006	Middle ear mold	Cetakan telinga tengah	C
007	Partial ossicular replacement prosthesis	Prostesis pengganti <i>ossicular</i> (rekonstruksi sebagian)	C
008	Total ossicular replacement prosthesis	Prostesis pengganti <i>ossicular</i> (rekonstruksi total)	C
009	Prosthesis modification instrument for ossicular replacement surgery	Prostesis modifikasi untuk pengganti <i>ossicular</i>	A
010	Ear, nose, and throat synthetic polymer material	Polimer sintesis sebagai bahan rekonstruksi THT	C
011	Mandibular implant facial prosthesis	Implan untuk rekonstruksi mandibular	C
012	Laryngeal prosthesis (Taub design)	Prostesis laring	C
013	Sacculotomy tack (Cody tack)	Paku <i>sacculotomy</i>	C
014	Endolymphatic shunt	<i>Shunt</i> endolimpatik	C
015	Endolymphatic shunt tube with valve	<i>Shunt</i> endolimpatik dengan katup	C
016	Tympanostomy tube	<i>Malleous clip tube, tympanostomy tube</i>	C
017	Nasal dilator	Dilator nasal / hidung	A
018	Tympanostomy tube with semipermeable membrane	<i>Malleous clip tube</i> dengan membran semipermeabel	C
019	Transcutaneous air conduction hearing aid system	Alat bantu dengar transkutan rambatan udara (implan)	C
020	Hearing Aid (bone conduction)	Alat bantu dengar ( <i>bone</i> )	B

		<i>conduction)</i>	
021	Cochlear implant	Implan koklea	D
022	Battery-powered artificial larynx.	Laring artifisial tenaga baterai	B
023	Wireless air-conduction hearing aid	Alat bantu dengar dengan teknologi nirkabel	B
024	Tympanic membrane contact hearing aid	Alat bantu dengar membran timpani	C
025	Self-fitting air-conduction hearing aid	Alat bantu dengar konduksi udara otomatis	B
026	Active implantable bone conduction hearing system.	Alat bantu dengar konduksi tulang implan aktif	C

## 07. Peralatan Telinga, Hidung, dan Tenggorokan

### 03. Peralatan THT Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Ear, nose, and throat electric or pneumatic surgical drill.	<i>Drill</i> THT elektrik atau pneumatik	B
002	Ear, nose, and throat fiberoptic light source and carrier	Sumber cahaya serat optik untuk THT	A
003	Ear, nose, and throat manual surgical instrument.	Instrumen bedah THT manual	A
004	Argon laser for otology, rhinology, and laryngology.	Laser argon untuk aplikasi otologi, rinologi, dan laringologi	C
005	Ear, nose, and throat microsurgical carbon dioxide laser.	Laser CO <sub>2</sub> untuk THT	C
006	Bronchoscope (flexible or rigid) and accessories.	Bronkoskop dan aksesoris	B
007	Esophagoscope (flexible or rigid) and accessories.	Esofagoskop dan aksesoris	B
008	Mediastinoscope and accessories.	Mediastinoskop dan aksesoris	B
009	Nasopharyngoscope (flexible or rigid) and accessories.	Nasofaringoskop dan aksesoris	B
010	Otoscope	Otoskop	A
011	Intranasal splint	<i>Splint</i> intranasal	A

012	Bone particle collector	Alat penyaring untuk mengumpulkan partikel tulang	A
013	Epistaxis balloon	Balon untuk mengendalikan pendarahan hidung internal	A
014	Ear, nose, and throat bur	Bor THT	A
015	Nasopharyngeal catheter	Kateter nasofaring	B
016	Laryngostroboscope	Laringostroboskop	B
017	Eustachian tube balloon dilation system.	Sistem pelebaran balon tabung <i>eustachius</i>	C

## 07. Peralatan Telinga, Hidung, dan Tenggorokan

### 04. Peralatan THT Terapetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Ear, nose, and throat drug administration device	Alat penghantar obat THT	A
002	Suction antichoke device (manual)	Alat penghisap anti sedak manual	A
003	Suction antichoke device (electric)	Alat penghisap anti sedak elektrik	B
004	Tongs antichoke device	Alat penjepit anti sedak	B
005	Powered nasal irrigator	Irigator hidung elektrik	A
006	External nasal splint.	<i>Splint</i> nasal eksternal	A
007	Nasal irrigation solution	Larutan irigasi hidung	B
008	Nasal irrigator	Irigator hidung	A
009	Speech training for the hearing impaired aids ( <i>AC-powered and patient-contact</i> )	Alat latihan bicara untuk gangguan pendengaran (elektrik dan kontak pasien)	B
010	Speech training for the hearing impaired aids ( <i>battery-operated or non- patient contact</i> )	Alat latihan bicara untuk gangguan pendengaran (sumber baterai atau tidak kontak pasien)	B
011	Vestibular analysis apparatus	Alat analisis vestibular (telinga bagian dalam)	B

012	Ear, nose, and throat examination and treatment unit.	Unit pemeriksaan dan perawatan THT	A
013	Antistammering device.	Alat <i>antistammering</i>	B
014	External upper esophageal sphincter compression device	Alat kompresi eksternal <i>sphincter</i> esofagus bagian atas	C

## 08. Peralatan Gastroenterologi-Urologi

### 01. Peralatan Gastroenterologi-Urologi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Gastroenterology-urology biopsy instrument ( <i>cover and non-electric</i> )	Instrumen biopsi gastroenterologi dan urologi ( <i>cover</i> dan non elektrik)	A
002	Gastroenterology-urology biopsy instrument ( <i>electric</i> )	Instrumen biopsi gastroenterologi dan urologi (elektrik)	B
003	Stomach pH electrode.	Elektrode pH lambung	A
004	Endoscope and accessories	Endoskopi dan aksesoris	B
005	Urodynamics measurement system.	Sistem pengukuran urodinamik	C
006	Gastrointestinal motility monitoring system.	Sistem pemantauan motilitas gastrointestinal	B
007	Electrogastrography system.	Sistem elektrogastrografi	C
008	Urine flow or volume measuring system.	Sistem pengukuran laju alir atau volume urin	C
009	Nasopharyngoscope (flexible or rigid) and accessories.	Nasofaringoskop (fleksibel atau <i>rigid</i> ) dan aksesoris	B
010	Ingestible telemetric gastrointestinal capsule imaging system.	Sistem pencitraan kapsul gastrointestinal telemetri yang dapat dicerna	C
011	Sexual Assessment Monitor	Alat pemantauan penilaian seksual	A
012	Gastroenterology-urology accessories to a biopsy instrument.	Aksesoris instrumen gastroenterologi dan urologi untuk biopsi	A
013	Colon capsule endoscopy system	Sistem endoskopi kapsul usus	C

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08. Peralatan Gastroenterologi-Urologi

02. Peralatan Gastroenterologi-Urologi Pemantauan

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Enuresis alarm	Alarm enuresis	B
002	Prostate lesion documentation system	Sistem dokumentasi lesi prostat	B

08. Peralatan Gastroenterologi-Urologi

03. Peralatan Gastroenterologi-Urologi Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Penile inflatable implant	Implan penis <i>inflatable</i>	D
002	Penile rigidity implant	Implan penis <i>rigid</i>	C
003	Testicular prosthesis.	Prostesis testis	D
004	Implanted Blood Access Device	Alat akses darah implan	D
005	Penile implant surgical accessories	Aksesori bedah implan penis	A

08. Peralatan Gastroenterologi-Urologi

04. Peralatan Gastroenterologi-Urologi Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Fiberoptic light ureteral catheter	Kateter ureter cahaya serat optik	C
002	Colostomy rod	Batang / <i>rod</i> kolostomi	C
003	Endoscopic electrosurgical unit and accessories	ESU endoskopi	C
004	Gastroenterology-urology evacuator (electric)	Evakuator gastroenterologi dan urologi (elektrik)	C
005	Gastroenterology-urology evacuator (manual)	Evakuator gastroenterologi dan urologi (manual)	A
006	Hemorrhoidal ligator	Ligator hemorrhoidal	C



007	Electrohydraulic lithotripter	<i>Lithotripter</i> elektrohidrolik	C
008	Mechanical lithotripter	<i>Lithotripter</i> mekanik	C
009	Gastroenterology-urology fiberoptic retractor	Retraktor gastroenterologi dan urologi serat optik	A
010	Ribdam	<i>Ribdam</i>	A
011	Interlocking urethral sound	<i>Interlocking urethral sound</i>	A
012	Ureteral stent	<i>Stent</i> ureter	B
013	Water jet renal stone dislodger system	Sistem penghancur batu ginjal dengan air bertekanan tinggi	C
014	Ureteral stone dislodger	Penghancur batu ginjal ureter	C
015	Manual gastroenterology-urology surgical instrument and accessories	Instrumen bedah gastroenterologi dan urologi manual dan aksesoris	A
016	Urethrotome	<i>Urethrotome</i>	C
017	Urological table and accessories (manual)	Meja urologi dan aksesoris manual	A
018	Urological table and accessories (electric)	Meja urologi dan aksesoris elektrik	B
019	Temporary replacement of glycosaminoglycan layer in the bladder	Lapisan pengganti sementara <i>glycosaminoglycan</i> di kandung kemih	D
020	Ureteral stent accessories	Aksesoris <i>stent</i> ureter	A
021	Fluid jet system for prostate tissue removal.	Sistem jet cairan untuk pengangkatan jaringan prostat	C

08. Peralatan Gastroenterologi-Urologi

05. Peralatan Gastroenterologi-Urologi Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Biliary catheter and accessories	Kateter empedu dan aksesoris	C

002	External penile rigidity devices	Perangkat penis <i>rigid</i> eksternal	C
003	Continent ileostomy catheter	Kateter ileostomi	A
004	Suprapubic urological catheter and accessories	Kateter urologi suprapubik dan aksesoris	C
005	Urological catheter and accessories	Kateter urologi dan aksesoris	C
006	Urological clamp for males	Klem urologi pria	A
007	Enema kit	Kit enema	A
008	Colonic irrigation system	Sistem irigasi usus besar	B
009	Urine collector and accessories (indwelling catheter)	Kantong penampung urin / <i>urine bag</i> dengan kateter	B
010	Implanted electrical urinary continence device	Alat implan pengendali inkontinensia urin (elektrik)	D
011	Implanted mechanical/hydraulic urinary continence device	Alat implan pengendali inkontinensia urin (mekanik/hidrolik)	D
012	Nonimplanted, peripheral electrical continence device	Alat non-implan pengendali inkontinensia periferal (elektrik)	B
013	Nonimplanted electrical continence device	Alat non-implan pengendali inkontinensia (elektrik)	B
014	Esophageal dilator	Dilator esofagus	B
015	Rectal dilator	Dilator rektal	A
016	Ureteral dilator	Dilator ureter	B
017	Urethral dilator	Dilator uretra	B
018	Blood access device and accessories.	Pengakses darah dan aksesoris	C
019	Sorbent regenerated dialysate delivery system for hemodialysis.	Sorben dialisis untuk hemodialisis	C
020	Peritoneal dialysis system and accessories	Sistem dialisis peritoneal dan aksesoris	C
021	Water purification system for hemodialysis	Pemurni air untuk hemodialisis	C
022	Hemodialysis system and accessories	Sistem hemodialisa dan aksesoris	C
023	Hemodialyzer with disposable insert	Hemodialisa tipe Kiil	C

	(Kiil type)		
024	High permeability hemodialysis system	Sistem hemodialisa permeabilitas tinggi	C
025	Sorbent hemoperfusion system for treatment of hepatic coma and metabolic disturbances	Sistem sorben hemoperfusi	D
026	Isolated kidney perfusion and transport system and accessories	Sistem perfusi dan transportasi ginjal dan aksesoris	B
027	Tissue culture media for human ex vivo tissue and cell culture processing applications	Media kultur jaringan untuk aplikasi pengolahan jaringan dan kultur sel manusia	B
028	Ostomy irrigator	Irigator ostomi / kolostomi	B
029	Ostomy pouch and accessories	Kantong ostomi / kolostomi dan aksesoris	A
030	Protective garment for incontinence	Garmen proteksi untuk inkontinensi, popok dewasa ( <i>adult diapers</i> )	A
031	Peritoneo-venous shunt	<i>Shunt</i> vena peritoneal	C
032	Hernia support	Korset hernia	A
033	Gastrointestinal tube and accessories	Selang gastrointestinal dan aksesoris	B
034	Extracorporeal shock wave lithotripter	ESWL	C
035	Medical gas yoke assembly	Sambungan gas medis <i>yoke</i>	B
036	Urine collector and accessories	Kantong penampung urin / <i>Urine bag</i>	A
037	Renal Denervation Catheter	Kateter renal	D
038	Sorbent hemoperfusion system	Sistem hemoperfusi sorben	C
039	Mucoadhesive suspension	Suspensi mukoadhesif	D
040	Pancreatic drainage stent and delivery system	<i>Stent</i> drainase pankreas dan sistem penghantarnya	C
041	Implanted mechanical/hydraulic urinary continence device surgical accessories	Aksesoris alat bedah implan untuk inkontinensia urin (mekanik/hidrolik)	A
042	Metallic biliary stent system for	Sistem <i>stent</i> bilier logam untuk	C

	benign strictures	struktur jinak	
043	Biliary stent, drain, and dilator accessories	Aksesori <i>stent</i> bilier, <i>drain</i> , dan dilator	A
044	Vibrator for climax control of premature ejaculation	Vibrator untuk mengontrol klimaks ejakulasi dini	C
045	Suprapubic catheter accessories	Aksesori kateter suprapubik	A
046	Urethral insert with pump for bladder drainage	<i>Insert</i> uretra dengan pompa untuk drainase kandung kemih	C
047	Implantable transprostatic tissue retractor system	Sistem retraktor jaringan transprostatik implan	C
048	Prostatic artery embolization device	Perangkat embolisasi arteri prostat	C
049	Prostatic artery embolization device (animal origin)	Perangkat embolisasi arteri prostat (mengandung bahan yang berasal dari hewan)	D
050	Rectal control system	Sistem kendali rektal	C
051	Oral removable palatal space occupying device for weight management and/or weight loss	Alat pengendali jumlah makanan yang dikonsumsi untuk mengontrol berat badan	C
052	Enzyme packed cartridge	Katrij berisi enzim	C

## 09. Peralatan Rumah Sakit Umum dan Perorangan

### 01. Peralatan RSUP Pemantauan

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Liquid crystal forehead temperature strip	Termometer dahi (strip)	B
002	Bed-patient monitor	Alat monitor keberadaan pasien di tempat tidur	A
003	Electronic monitor for gravity flow infusion systems	Monitor elektronik untuk sistem infus	B
004	Electrically powered spinal fluid	Monitor tekanan cairan spinal	B

	pressure monitor	elektrik	
005	Patient scale	Timbangan pasien (untuk pasien yang tidak dapat berdiri)	A
006	Stand-on patient scale	Timbangan pasien (untuk pasien yang dapat berdiri)	A
007	Sterilization process indicator	Indikator proses sterilisasi	B
008	Clinical electronic thermometer	Termometer digital	B
009	Apgar timer	Alat penilaian skor apgar	A
010	Jaundice meter	<i>Jaundice</i> meter	C
011	Spinal fluid manometer	Manometer cairan spinal	B
012	Surgical sponge scale	Timbangan spon bedah	A
013	Clinical color change thermometer	Termometer dengan indikator perubahan warna	B
014	Thermal imaging camera system	Kamera pendeteksi suhu tubuh	B
015	Image processing device for estimation of external blood loss.	Perangkat pengolah gambar untuk estimasi kehilangan darah eksternal	C

## 09. Peralatan Rumah Sakit Umum dan Perorangan

### 02. Peralatan RSUP Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	I.V. container	Kontainer infus, botol infus, <i>kolf</i> infus, kantong infus	B
002	Elastic bandage	Plester elastis, perban elastis	A
003	AC-powered adjustable hospital bed	Tempat tidur pasien elektrik	B
004	Hydraulic adjustable hospital bed	Tempat tidur pasien hidraulik	A
005	Manual adjustable hospital bed	Tempat tidur pasien manual	A
006	Infant radiant warmer	<i>Infant warmer, radiant warmer</i>	B
007	Pediatric hospital bed	Tempat tidur pasien anak	B
008	Nonpowered flotation therapy mattress	Matras terapi flotasi	A
009	Therapeutic medical binder	Penyangga yang ditempatkan di bagian tubuh untuk tujuan	A

		medis	
010	Burn sheet	Kasa penutup luka bakar	A
011	Intravascular catheter.	IV kateter, kateter intravaskular	C
012	Intravascular catheter securement device	Alat pengaman kateter intravaskular	A
013	Medical adhesive tape and adhesive bandage, sterile	Pita perekat medis dan perban perekat medis (steril)	A
014	Medical adhesive tape and adhesive bandage, non sterile	Pita perekat medis dan perban perekat medis (non steril)	A
015	Neonatal eye pad	Penutup mata untuk neonatus	A
016	Medical absorbent fiber	Kapas serap medis	A
017	Neonatal incubator	Inkubator neonatus, inkubator bayi	B
018	Neonatal transport incubator	Inkubator transport neonatus, inkubator bayi portabel	B
019	Pressure infusor for an I.V. bag	Alat pemberi tekanan pada kantong infus	A
020	Nonelectrically powered fluid injector	Alat injektor nonelektrik	B
021	Patient care reverse isolation chamber	<i>Chamber</i> isolasi untuk perawatan pasien	B
022	Jet lavage	Alat jet pulsatil untuk membersihkan luka dengan cairan steril	B
023	AC-powered patient lift	Alat bantu elektrik untuk mengangkat pasien	B
024	Alternating pressure air flotation mattress	Matras pencegahan dan perawatan <i>decubitus</i>	B
025	Hypodermic single lumen needle	Jarum suntik	B
026	Acupuncture needle	Jarum akupuntur	B
027	Nipple shield	Pelindung puting	A
028	Pediatric position holder	Alat penggendong bayi atau anak untuk tujuan terapeutik atau diagnostik	A

029	Neonatal phototherapy unit	Unit fototerapi neonatus	B
030	Infusion pump	Pompa infus	B
031	Suction snakebite kit	Kit <i>suction</i> untuk bisa gigitan ular	A
032	Chemical cold pack snakebite kit.	Kit perawatan pertolongan pertama gigitan ular	D
033	Medical support stocking	Stoking medis	A
034	Therapeutic scrotal support	Korset skrotum	A
035	Piston syringe.	Alat suntik sekali pakai, spuit	B
036	Umbilical occlusion device.	Alat untuk menutup pembuluh darah di tali pusat bayi baru lahir	A
037	Lice removal kit.	Kit penghilang kutu	A
038	Subcutaneous, implanted, intravascular infusion port and catheter	<i>Port</i> dan kateter infus intravaskular untuk diimplan subkutan	C
039	Percutaneous, implanted, long-term intravascular catheter	Kateter intravaskular untuk diimplan jangka panjang secara perkutan	C
040	Pediatric hospital bed	Tempat tidur anak	B
041	Intravascular administration set	Infus set, termasuk <i>three way slang, three way stop cock</i>	C
042	Medical recirculating air cleaner	Pembersih udara resirkulasi	B
043	Liquid bandage.	Perban cair	B
044	Non-AC-powered patient lift	Pengangkat pasien manual	A
045	Temperature regulated water mattress	Matras air dengan pengatur suhu	B
046	Lamb feeding nipple	Alat bantu menyusui untuk bayi dengan kelainan oral	B
047	Implanted programmable infusion pump	Pompa infus yang diimplan	D
048	Pediatric medical crib	Boks medis anak	B
049	Medical bassinet	Keranjang medis	B

050	Intravascular administration set, automated air removal system	Infus set dengan sistem pembuangan udara otomatis	C
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09. Peralatan Rumah Sakit Umum dan Perorangan

03. Peralatan RSUP Lainnya

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Absorbent tipped applicator	Kapas batang	A
002	Ice bag	Kantong es untuk kompres	A
003	Medical disposable bedding	Alas tempat tidur medis sekali pakai	A
004	Bed board	Papan tempat tidur	A
005	Cardiopulmonary resuscitation board	Papan CPR	A
006	Hot/cold water bottle	Botol air panas / dingin untuk kompres	A
007	Ethylene oxide gas aerator cabinet	Kabinet aerator gas etilen oksida	B
008	Medical chair and table	Kursi dan meja medis	A
009	Cast cover	Penutup gips	A
010	Mattress cover for medical purposes	Penutup matras medis	A
011	Ring cutter	Pemotong cincin	A
012	Tongue depressor	Sudip lidah, spatel lidah	A
013	Filtering facepiece respirator for use by the general public in public health medical emergencies	<i>Filtering facepiece respirator (FFP)</i>	B
014	Examination gown	Baju pemeriksaan	A
015	Medical insole	<i>Insole</i> medis	A
016	Implantable radiofrequency transponder system for patient identification and health information.	Sistem transponder frekuensi radio implan untuk identifikasi pasien dan informasi kesehatan	C
017	AC-powered medical examination light	Lampu periksa elektrik, lampu periksa pasien	A



018	Battery-powered medical examination light	Lampu periksa dengan baterai	A
019	Liquid medication dispenser	Dispenser obat cair	A
020	Skin pressure protectors.	Pelindung tekanan kulit	A
021	Medical ultraviolet air purifier	Alat pemurnian udara medis dengan ultraviolet	B
022	Medical ultraviolet water purifier	Alat pemurnian air medis dengan ultraviolet , <i>scrub station with UV</i>	B
023	Body waste receptacle	Wadah penampung limbah tubuh	A
024	Vacuum-powered body fluid suction apparatus	Perangkat penghisap cairan tubuh dengan tenaga vakum	B
025	Protective restraint	Straps pengekang tubuh pasien	A
026	Powered patient transfer device	Brankar elektrik	B
027	Manual patient transfer device	Brankar manual	A
028	Washers for body waste receptacles	Pencuci wadah limbah tubuh	A
029	Medical disposable scissors	Gunting medis sekali pakai	A
030	Sterilization wrap	Pembungkus/wadah untuk proses steril	B
031	Ethylene oxide gas sterilizer	Alat pensteril dengan gas etilen oksida	B
032	Dry-heat sterilizer	Alat pensteril dengan panas-kering	B
033	Steam sterilizer	Alat pensteril dengan uap / autoclave	B
034	Liquid chemical sterilants/high level disinfectants	Sterilan kimia cair / disinfektan tingkat tinggi	B
035	Hand-carried stretcher	Tandu lipat	A
036	Wheeled stretcher	Tandu beroda, brankar ambulan	B
037	Syringe needle introducer	Alat untuk memasukkan jarum suntik	B
038	Liquid crystal vein locator	Alat untuk menunjukkan	A

		lokasi vena	
039	Vein stabilizer	<i>Stabilizer vena</i>	A
040	Infusion stand	Tiang infus	A
041	Medical washer	Alat untuk membersihkan dan mengeringkan instrumen	B
042	Medical washer-disinfector	Alat mendisinfeksi dan mencuci instrumen	B
043	Infusion fluid thermal warmer	Alat penghangat cairan infus	B
044	Warming cabinets	Lemari penghangat	B
045	Patient lubricant	Pelumas untuk pasien	B
046	Alcohol swab	Alkohol swab, kapas alkohol	B
048	Hydrogen Peroxide Sterilizer	Alat pensteril dengan <i>Hydrogen Peroxide</i> (H <sub>2</sub> O <sub>2</sub> )	B
049	Needle destruction device	Alat penghancur jarum	B
050	Sharp container	Wadah limbah jarum	B
051	Blood or fluid warming system	Sistem penghangat darah atau cairan	B
052	Plasma Sterilizer	Alat pensteril dengan plasma	B
053	Medical Waste Destroyer	Penghancur limbah medis	B
054	Germicidal ultraviolet device	Alat UV germisidal	B
055	Finger Cot	Sarung jari tangan	B
056	Ingestible Event Marker	Alat penanda waktu yang ditelan untuk merekam fungsi aktifitas tubuh	C
057	Pill Crusher/Cutter	Alat pemotong obat	A
060	Ultrasonic cleaner for medical instruments	Pembersih ultrasonik untuk instrumen medis	B
061	Patient examination glove	Sarung tangan	A
064	General purpose disinfectants	Disinfektan untuk penggunaan umum (alat kesehatan dan permukaannya)	B
065	Irrigating syringe	Sputir irigasi	B
066	Medical device data system	Sistem data perangkat medis	B
067	Ultraviolet (UV) radiation chamber	Sterilisator UV	B

	disinfection device		
068	Enzyme cleaning solution	Cairan pembersih alat kesehatan dengan enzim	B
069	Alcohol swab with numbing agent	Swab alkohol dengan anestesi	C
070	Antiseptic with Numbing Agent	Cairan antiseptik dengan anestesi	C
071	Sharps needle destruction device	Alat penghancur jarum	B
072	Patient examination glove	Sarung tangan pemeriksaan	A
073	Remote Medication Management System	Sistem manajemen pengobatan jarak jauh	B
074	Holder syringe adaptor	Adaptor pemegang syringe	A

## 10. Peralatan Neurologi

### 01. Peralatan Neurologi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Rigidity analyzer	Alat analisa tingkat kekakuan anggota tubuh pasien	B
002	Ataxiagraph	Ataxiagraf	A
003	Two-point discriminator	Alat uji diskriminasi sentuhan	A
004	Echoencephalograph	Ekoensefalograf	B
005	Electroconductive media	Elektrokonduktif	B
006	Cortical electrode	Elektroda kortikal	B
007	Cutaneous electrode	Elektroda kulit	B
008	Depth electrode	Elektroda stimulasi atau perekaman sinyal listrik di bawah permukaan otak	C
009	Nasopharyngeal electrode	Elektroda nasofaring	B
010	Needle electrode	Elektroda jarum	B
011	Electroencephalograph	EEG	B
012	Electroencephalograph electrode/lead tester	Elektroda EEG	A

013	Electroencephalogram (EEG) signal spectrum analyzer	Alat analisa spektrum sinyal EEG	A
014	Electroencephalograph test signal generator	Generator sinyal uji EEG	A
015	Nystagmograph	Nistagmograf	B
016	Neurological endoscope	Endoskopi pada syaraf	B
017	Esthesiometer	<i>Esthesiometer</i> , alat uji sensitivitas sentuh	A
018	Tuning fork	Garpu tala	A
019	Galvanic skin response measurement device	Alat pengukur respon kulit galvanis	B
020	Nerve conduction velocity measurement device	Alat pengukur kecepatan konduksi saraf	B
021	Skin potential measurement device	Alat pengukur potensial kulit	B
022	Powered direct-contact temperature measurement device	Alat pengukur suhu elektrik	B
023	Alpha monitor	Monitor gelombang alfa	B
024	Intracranial pressure monitoring device	Alat pemantau tekanan intrakranial	C
025	Percussor	Palu perkusor	A
026	Pinwheel	<i>Pinwheel</i> , alat uji sensasi rasa nyeri	A
027	Ocular plethysmograph	Pletismograf okular	C
028	Rheoencephalograph	<i>Rheoencephalograph</i> , alat untuk memperkirakan sirkulasi aliran darah di otak	C
029	Physiological signal amplifier	Penguat sinyal fisiologis	B
030	Physiological signal conditioner	Pengkondisi sinyal fisiologis	B
031	Electroencephalogram (EEG) telemetry system	Sistem telemetri EEG	C
032	Evoked response electrical stimulator	Stimulator listrik pembangkit respon	B
033	Evoked response mechanical stimulator	Stimulator mekanik pembangkit respon	B

034	Evoked response photic stimulator	Stimulator cahaya pembangkit respon	C
035	Evoked response auditory stimulator	Stimulator suara pembangkit respon	B
036	Ultrasonic scanner calibration test block	Blok kalibrator untuk pemindai ultrasonik	A
037	Tremor transducer	Transduser pengukur tremor	C
038	Near Infrared (NIR) Brain Hematoma Detector	Detektor <i>near infrared</i> (NIR) hematoma otak	C

## 10. Peralatan Neurologi

### 02. Peralatan Neurologi Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Ventricular catheter	Kateter ventrikel	C
002	Neurosurgical chair	Kursi bedah saraf	A
003	Scalp clip	Scalp klip (klip pada kulit kepala)	B
004	Aneurysm clip applier	Aplikator klip aneurisma	B
005	Clip forming/cutting instrument	Instrumen pemotong klip	A
006	Clip removal instrument	Instrumen pelepas klip	A
007	Clip rack	Rak klip	A
008	Cryogenic surgical device	Alat bedah <i>cryogenic</i>	B
009	Dowel cutting instrument	Alat pemotong tulang	B
010	Manual cranial drills, burrs, trephines, and their accessories	Alat pemotong dan pengebor tulang (trefin, gerinda, dll) manual	B
011	Powered compound cranial drills, burrs, trephines, and their accessories	Alat pemotong dan pengebor tulang (trefin, gerinda, dll) <i>powered compound</i>	B
012	Powered simple cranial drills, burrs, trephines, and their accessories	Alat pemotong dan pengebor tulang (trefin, gerinda, dll) <i>powered simple</i>	B
013	Cranial drill handpiece (brace)	Bor kranial	A
014	Electric cranial drill motor	Bor kranial elektrik	B
015	Pneumatic cranial drill motor	Bor kranial pneumatik	B

016	Radiofrequency lesion generator	Generator lesi (luka) bersumber radiofrekuensi	B
017	Neurosurgical headrests	Sandaran kepala pada bedah saraf	A
018	Neurosurgical head holder (skull clamp)	Penjepit tengkorak pada bedah saraf	B
019	Cranioplasty material forming instrument	Instrumen pembentuk material <i>cranioplasty</i>	A
020	Microsurgical instrument	Instrument bedah minor	A
021	Nonpowered neurosurgical instrument	Instrumen bedah saraf (non elektrik)	A
022	Shunt system implantation instrument	Instrument implan pada sistem <i>shunt</i>	A
023	Stereotaxic instrument	Instrumen stereotaksik	B
024	Leukotome	Leukotom	A
025	Neurosurgical suture needle.	Jarum jahit bedah saraf	A
026	Neurosurgical paddie.	<i>Pad</i> bedah saraf	B
027	Radiofrequency lesion probe.	Probe lesi (luka) radiofrekuensi	B
028	Skull punch.	Alat pelubang tengkorak pasien	A
029	Self-retaining retractor for neurosurgery.	Retraktor untuk bedah saraf	B
030	Manual rongeur.	<i>Rongeur</i> manual	B
031	Powered rongeur.	<i>Rongeur</i> elektrik	B
032	Skullplate screwdriver.	Obeng plat tengkorak	A
033	Neurovascular stent	<i>Stent</i> neurovaskular	D
034	Skull plate anvil.	Alat cetak plat tengkorak	A
035	Ventricular cannula.	Kanula ventrikel	A
036	Intratechal catheter	Kateter intratekal	D

## 10. Peralatan Neurologi

### 03. Peralatan Neurologi Terapetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Methyl methacrylate for aneurysmorrhaphy	Metil metakrilat untuk <i>aneurysmorrhaphy</i>	C

002	Biofeedback device	Instrumen penangkap sinyal audio / visual untuk parameter fisiologi pasien	B
003	Bite block	<i>Bite block</i>	B
004	Intravascular occluding catheter	Kateter oklusi intravaskular	D
005	Carotid artery clamp.	Penjepit arteri karotid	B
006	Aneurysm clip	Klip aneurisma	B
007	Implanted malleable clip	Klip implan <i>malleable</i>	C
008	Aversive conditioning device	Instrumen yang digunakan untuk memberikan kejutan listrik	C
009	Burr hole cover	Penutup lubang tengkorak	C
010	Nerve cuff	Manset pada saraf	B
011	Methyl methacrylate for cranioplasty	Metil metakrilat untuk <i>cranioplasty</i>	C
012	Preformed alterable cranioplasty plate	Plat <i>cranioplasty</i> siap pakai yang dapat diubah	C
013	Preformed nonalterable cranioplasty plate	Plat <i>cranioplasty</i> siap pakai yang tidak dapat diubah	C
014	Cranioplasty plate fastener	Pengencang / pengikat plat untuk <i>cranioplasty</i>	C
015	Lesion temperature monitor	Monitor suhu pada luka	B
016	Central nervous system fluid shunt and components	Pemindah cairan sistem saraf pusat, <i>VP Shunt</i>	C
017	External functional neuromuscular stimulator	Stimulator neuromuskuler fungsional eksternal	C
018	Implanted cerebellar stimulator	Implan stimulator <i>cerebellar</i>	D
019	Implanted diaphragmatic/phrenic nerve stimulator	Implan stimulator saraf <i>diaphragmatic / phrenic</i>	D
020	Implanted intracerebral/subcortical stimulator for pain relief	Implan stimulator <i>intracerebral / subcortical</i> untuk menghilangkan rasa sakit	D
021	Implanted spinal cord stimulator for bladder evacuation	Implan stimulator sumsum tulang belakang untuk evakuasi kandung kemih	D

022	Implanted neuromuscular stimulator	Implan stimulator saraf otot	D
023	Implanted peripheral nerve stimulator for pain relief	Implan stimulator saraf perifer untuk menghilangkan rasa sakit	C
024	Implanted spinal cord stimulator for pain relief	Implan stimulator sumsum tulang belakang untuk menghilangkan rasa sakit	D
025	Spinal cord stimulator for pain relief	Stimulator sumsum tulang belakang untuk menghilangkan rasa sakit	B
026	Transcutaneous electrical nerve stimulator for pain relief	Stimulator transkutan elektrik untuk menghilangkan rasa sakit	B
027	Preformed craniostomosis strip	Strip <i>craniostomosis</i> siap pakai	B
028	Dura substitute.	Material pengganti dura	B
029	Electroconvulsive therapy device	Alat ECT	D
030	Neurovascular embolization device	Alat embolisasi neurovaskular	C
031	Skull tongs for traction	Penjepit tengkorak	B
032	Cranial orthosis	Ortosis <i>cranial</i>	C
033	Human dura mater	<i>Human dura mater</i>	C
034	Repetitive transcranial magnetic stimulation system	Sistem stimulasi magnetik transkranial	B
035	Implanted neurovascular embolization device	Alat implan embolisasi neurovaskular	D
036	Implantable multi-programmable quadripolar deep brain stimulation system	Sistem stimulator otak dalam quadripolar multi-program yang diimplan	D
037	Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites	Stimulator <i>piezoelectric</i> transkutan untuk reaksi kulit yang berhubungan dengan gigitan serangga	C
038	Peripheral Stent	<i>Stent</i> perifer	D
039	Cranial electrotherapy stimulator	Stimulator elektroterapi <i>cranial</i>	B



040	Electro acupuncture	Alat akupuntur elektrik	A
041	Carotid stent	<i>Carotid stent</i>	D

## 11. Peralatan Obstetrik dan Ginekologi

### 01. Peralatan Obstetrik dan Ginekologi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Endocervical aspirator	Aspirator endoserviks	B
002	Endometrial aspirator	Aspirator endometrium	C
003	Endometrial brush	Sikat endometrium	C
004	Endometrial suction curette and accessories	Alat kuret hisap endometrium dan aksesoris	B
005	Endometrial washer	Pencuci endometrium	C
006	Uterotubal carbon dioxide insufflator and accessories	<i>Insufflator</i> karbon dioksida uterotubal dan aksesoris	B
007	Perineometer	<i>Perineometer</i>	B
008	Amniotic fluid sampler (amniocentesis tray)	Alat pengambil sampel cairan ketuban (baki <i>amniocentesis</i> )	A
009	Fetal blood sampler	Alat pengambil sampel darah janin	B
010	Transabdominal amnioscope (fetoscope) and accessories	<i>Amnioscope</i> transabdominal ( <i>fetoscope</i> ) dan aksesoris	D
011	Colposcope	<i>Colposcope</i>	B
012	Culdoscope and accessories	<i>Culdoscope</i> dan aksesoris	B
013	Transcervical endoscope (amnioscope) and accessories	Endoskopi trans servikal ( <i>amnioscope</i> ) dan aksesoris	B
014	Hysteroscope and accessories	<i>Hysteroscope</i> dan aksesoris	B
015	Hysteroscopic insufflator.	<i>Insufflator</i> histeroskopi	B
016	Gynecologic laparoscope and accessories.	Laparoskop ginekologi dan aksesoris	B
017	Laparoscopic insufflator	<i>Insufflator</i> laparoskopi	B
018	Fertility diagnostic proceptive device	Perangkat diagnostik untuk kesuburan	B
019	Breast ductoscope	<i>Ductoscope</i>	B
020	Fallopiscope	<i>Fallopiscope</i>	B
021	Hysteroscopy fluid	Cairan histeroskopi	B

022	Viscometer for cervical mucus	Viskometer untuk lendir serviks	A
023	Obstetrics and Gynecology Camera	Kamera obgyn	B
024	Closed loop hysteroscopic insufflator with cutter-coagulator	<i>Insufflator</i> histeroskopi dengan pemotong dan koagulator	C

## 11. Peralatan Obstetrik dan Ginekologi

### 02. Peralatan Obstetrik dan Ginekologi Pemantauan

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Obstetric data analyzer.	Alat analisa data obstetri	D
002	Obstetric-gynecologic ultrasonic imager.	Alat untuk menampilkan gambar obstetri dan ginekologi	B
003	Fetal cardiac monitor.	Monitor jantung janin	B
004	Fetal electroencephalographic monitor	Monitor elektroensefalografi janin	D
005	Fetal phonocardiographic monitor and accessories	Monitor fonokardiografi janin dan aksesoris	B
006	Fetal ultrasonic monitor and accessories	Monitor ultrasonik janin dan aksesoris	B
007	Fetal scalp circular (spiral) electrode and applicator	Elektroda dan aplikator melingkar (spiral) kulit kepala janin	B
008	Fetal scalp clip electrode and applicator	Elektroda dan aplikator klip kulit kepala janin	D
009	Intrauterine pressure monitor and accessories	Monitor tekanan intrauterin dan aksesoris	B
010	External uterine contraction monitor and accessories	Monitor kontraksi uterus eksternal dan aksesoris	B
011	Home uterine activity monitor	Monitor aktivitas uterus	C
012	Perinatal monitoring system and accessories	Sistem pemantauan perinatal dan aksesoris	B
013	Computerized Labor Monitoring System	Sistem pemantauan proses persalinan	C
014	Fetal stethoscope	Stetoskop janin	A
015	Obstetric ultrasonic transducer and	Transduser ultrasonik obstetri	B

	accessories	dan aksesoris	
016	Breast lesion documentation system	Sistem dokumentasi lesi payudara	C
017	Fetal acoustical holograph	Holograf fetus akustik	B
018	Vaginal mold	Cetakan vagina	B
019	Fetal pulse oximeter	Oksimeter fetus	D
020	Telethermographic system for use alone in diagnostic screening	Sistem teletermografi untuk diagnostik secara mandiri	C
021	Telethermographic system for adjunctive diagnostic screening	Sistem teletermografi untuk diagnostik tambahan	A
022	Liquid crystal thermographic system for use alone in diagnostic screening	Sistem termografi <i>liquid crystal</i> untuk diagnostik secara mandiri	D
023	Liquid crystal thermographic system for adjunctive use in diagnostic screening	Sistem termografi <i>liquid crystal</i> untuk diagnostik tambahan	A

### 11. Peralatan Obstetrik dan Ginekologi

#### 03. Peralatan Obstetrik dan Ginekologi Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Cervical drain	<i>Cervical drain</i>	C
002	Vaginal pessary	Alat penyangga pada vagina	B
003	Fallopian tube prosthesis	Prostesis tuba fallopi	C
004	Vaginal stent	<i>Stent vagina</i>	B

### 11. Peralatan Obstetrik dan Ginekologi

#### 04. Peralatan Obstetrik dan Ginekologi Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Endoscopic electrocautery and accessories	Alat pemotong endoskopi elektrik dan aksesoris	C
002	Gynecologic electrocautery and accessories	Alat pemotong ginekologi elektrik dan aksesoris	B

003	Bipolar endoscopic coagulator-cutter and accessories	Pemotong dan koagulator endoskopi bipolar dan aksesori	C
004	Unipolar endoscopic coagulator-cutter and accessories	Pemotong dan koagulator endoskopi unipolar dan aksesori	C
005	Hygroscopic laminaria cervical dilator	Laminaria higroskopi	C
006	Fetal vacuum extractor	Ekstraktor vakum janin	C
007	Obstetric forceps	<i>Forcep</i> obstetri	C
008	Obstetric fetal destructive instrument	Instrumen obstetri destruktif janin	B
009	Obstetric-gynecologic general manual instrument	Instrumen obgin manual umum	A
010	Obstetric-gynecologic specialized manual instrument	Instrumen obgin manual khusus	B
011	Gynecologic surgical laser	Laser bedah ginekologi	B
012	Obstetric table and accessories	Meja obstetri dan aksesori	B
013	Absorbable Adhesion Barrier	<i>Barrier</i> adhesi yang diserap	D
014	Culdocentesis Kit	Kit <i>culdosentesis</i>	C
015	Hysterectomy Kit	Kit histerektomi	B
016	Labor And Delivery Kit	Kit untuk proses persalinan	B
017	Obstetrical Vacuum Delivery Kit	Kit untuk proses persalinan vakum	B
018	Expandable cervical dilator	Dilator serviks yang dapat diperpanjang	C
019	Vibratory cervical dilators	Dilator serviks yang bergetar	C
020	Gynecologic laparoscopic power morcellation containment system	Sistem penahan menggunakan power <i>morcellation</i> dalam prosedur laparoskopi ginekologi	C
021	Fetal head elevator	Elevator kepala fetus	C
022	Specialized surgical instrumentation for use with urogynecologic surgical mesh	Instrumen bedah khusus digunakan dengan mesh uroginekologi	C

11. Peralatan Obstetrik dan Ginekologi  
05. Peralatan Obstetrik dan Ginekologi Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Metreurynter-balloon abortion system	Sistem aborsi balon <i>metreurynter</i>	D
002	Vacuum abortion system	Sistem aborsi vakum	B
003	Obstetric anesthesia set	Set anestesi obstetri	B
004	Nonpowered breast pump	Pompa ASI manual	A
005	Powered breast pump	Pompa ASI elektrik	B
006	Abdominal decompression chamber	<i>Chamber</i> dekompresi perut	D
007	Cervical cap	Penutup serviks	B
008	Condom	Kondom	C
009	Condom with spermicidal lubricant	Kondom dengan pelumas	C
010	Glans sheath	Alat selubung kepala penis	D
011	Female condom	Kondom wanita	D
012	Contraceptive diaphragm and accessories	Kontrasepsi diafragma dan aksesoris	B
013	Contraceptive intrauterine device (IUD) and introducer	Alat kontrasepsi intrauterin dan penghantar	D
014	Contraceptive tubal occlusion device (TOD) and introducer	Alat kontrasepsi tuba oklusi dan penghantar	D
015	Perineal heater	Pemanas perineum	C
016	Menstrual cup	Cawan menstruasi	C
017	Scented or scented deodorized menstrual pad	Pembalut wanita dengan parfum	A
018	Unscented menstrual pad	Pembalut wanita tanpa parfum	A
019	Scented or scented deodorized menstrual tampon	Tampon wanita dengan parfum	B
020	Unscented menstrual tampon	Tampon wanita tanpa parfum	B
021	Therapeutic vaginal douche apparatus	Peralatan <i>douche</i> terapi vagina	B

022	Powered vaginal muscle stimulator for therapeutic use	Stimulator otot vagina untuk terapi	D
023	Genital vibrator for therapeutic use	Vibrator genital untuk terapi	B
024	Clitoral engorgement device	Alat pembesar klitoris	C
025	Condom lubricant	Pelumas kondom	B
026	Home use conception-assist kit	Kit Alat bantu kontrasepsi secara mandiri	B
027	Pelvic exam kit	Kit tes panggul	B
028	Interlabial pad	<i>Interlabial pad</i>	A
029	Vaginal insufflator	<i>Insufflator vagina</i>	B
030	Contraceptive diaphragm and accessories	Diafragma untuk kontrasepsi dan aksesoris	C
031	Hemorrhoid prevention pressure wedge	Alat penekan untuk pencegahan wasir	C
032	Pressure wedge for the reduction of cesarean delivery	Alat penekan untuk mengurangi persalinan secara cesar	C
033	Multiple-use female condom	Kondom wanita <i>reusable</i>	D
034	Single-use internal condom	Kondom wanita sekali pakai	C
035	Software application for contraception	Aplikasi perangkat lunak untuk kontrasepsi	C
036	Surgical mesh for transvaginal pelvic organ prolapse repair	Mesh bedah untuk organ panggul transvaginal	D

## 11. Peralatan Obstetrik dan Ginekologi

### 06. Peralatan Bantu Reproduksi

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Assisted reproduction needles	Jarum alat bantu reproduksi	B
002	Assisted reproduction catheters	Kateter alat bantu reproduksi	B
003	Assisted reproduction microtools	Alat mikro alat bantu reproduksi	B
004	Assisted reproduction micropipette	Mikro pipet alat bantu	B

	fabrication instruments	reproduksi	
005	Assisted reproduction micromanipulators and microinjectors	Mikro manipulator dan mikro injektor alat bantu reproduksi	B
006	Assisted reproduction labware	Alat laboratorium untuk alat bantu reproduksi	B
007	Assisted reproduction water and water purification systems	Sistem pemurnian air dan air untuk alat bantu reproduksi	B
008	Reproductive media and supplements	Media reproduksi dan suplemen	B
009	Assisted reproductive microscopes and microscope accessories	Mikroskop dan aksesoris alat bantu reproduksi	A
010	Assisted reproduction laser system	Sistem laser alat bantu reproduksi	C
011	Assisted reproduction accessories	Aksesoris alat bantu reproduksi	B
012	Intravaginal culture system	Sistem kultur intravaginal	C
013	Assisted Reproduction Embryo Image Assessment System	Sistem penilaian gambar embrio alat bantu reproduksi	C

## 12. Peralatan Mata

### 01. Peralatan Mata Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Ocular esthesiometer	Esthesiometer okular/ Alat penilai sensitivitas kornea	A
002	Adaptometer (biophotometer)	Biofotometer	A
003	Anomaloscope	Anomaloskop	A
004	Haidinger brush	<i>Haidinger brush</i>	A
005	Ophthalmic camera	Kamera mata	B
006	Ophthalmic chair	Kursi periksa mata	A
007	Visual acuity chart	<i>Snellen chart</i>	A
008	Color vision plate illuminator	Plat <i>illuminator</i> penglihatan warna	A

009	Color vision tester	Penguji penglihatan warna	A
010	Distometer	Distometer/Alat untuk mengukur jarak antara kornea dan lensa korektif	A
011	Optokinetic drum	Drum optokinetik/ Alat untuk memperoleh dan mengevaluasi <i>nystagmus</i> pada pasien	A
012	Corneal electrode	Elektroda kornea/ Alat untuk memberikan data yang menunjukkan perubahan potensial listrik di retina setelah elektoretinografi (stimulasi oleh cahaya)	B
013	Euthyscope	Alat yang digunakan dalam pengobatan ambliopia	A
014	Exophthalmometer	Alat untuk mengukur tingkat <i>exophthalmos</i>	A
015	Fixation device	Alat fiksasi	A
016	Afterimage flasher	Lampu untuk uji <i>afterimage</i>	B
017	Fornixscope	<i>Fornixscope</i>	A
018	Amsler grid	Kisi <i>amsler</i>	A
019	Haploscope	Haploskop	A
020	Keratoscope	Keratoskop	A
021	Visual field laser instrument	Instrumen laser bidang visual	B
022	Bagolini lens	Lensa <i>Bagolini</i>	A
023	Diagnostic condensing lens	Lensa kondensasi diagnostik	A
024	Polymethylmethacrylate (PMMA) diagnostic contact lens	PMMA kontak lensa diagnostik	B
025	Flexible diagnostic Fresnel lens	Lensa <i>Fresnel</i> diagnostik yang fleksibel untuk pasien <i>aphakia</i>	A
026	Diagnostic Hruby fundus lens	Lensa fundus <i>Hruby</i> diagnostik	A
027	Maddox lens	Lensa <i>Maddox</i>	A
028	Ophthalmic trial lens set	Set lensa uji mata	A



029	Ophthalmic trial lens clip	Klip lensa uji mata	A
030	Ophthalmic trial lens frame	Bingkai lensa uji mata	A
031	Ophthalmic lens gauge	Alat ukur lensa mata	A
032	Lens measuring instrument	Alat pengukur lensa	A
033	Ophthalmic contact lens radius measuring device	Alat ukur diameter kontak lensa mata	A
034	Maxwell spot	Alat uji fungsi makula mata	A
035	Corneal radius measuring device	Alat ukur diameter kornea	A
036	Stereopsis measuring instrument	Alat ukur stereopsis	A
037	Headband mirror	Ikat kepala penahan lampu pemeriksaan	A
038	Eye movement monitor	Monitor pergerakan mata	B
039	Ophthalmoscope	Optalmoskop	B
040	Perimeter	Perimeter	A
041	AC-powered photostimulator	Fotostimulator elektrik	B
042	Ophthalmic preamplifier	Preamplifier mata	B
043	Ophthalmic bar prism	Batang prisma mata	A
044	Ophthalmic Fresnel prism	Prisma <i>Fresnel</i> mata	A
045	Gonioscopic prism	Prisma gonioskopik	A
046	Ophthalmic rotary prism	Prisma putar mata	A
047	Ophthalmic isotope uptake probe	Probe serapan radioisotop pada mata	B
048	Ophthalmic projector	Proyektor mata	A
049	Pupillograph	Alat ukur respon pupil mata	A
050	Pupillometer	Alat ukur diameter pupil mata	A
051	Skiascopic rack	Rak <i>skiascopic</i>	A
052	Ophthalmic refractometer	Refraktometer mata	A
053	Manual refractor	Refraktor manual	A
054	Retinoscope	Retinoskop	B
055	Nearpoint ruler	Alat ukur titik dekat konvergensi mata	A
056	Schirmer strip	Strip <i>Schirmer</i> untuk merangsang keluarnya air mata	A
057	Tangent screen (campimeter)	Layar singgung ( <i>campimeter</i> )	A

058	Simulatan (including crossed cylinder)	Simulatan (silinder silang) yang memberi kekuatan bias plus dan minus	A
059	AC-powered slitlamp biomicroscope	Slitlamp biomikroskop	B
060	Ophthalmic instrument stand	Dudukan instrumen mata	A
061	Stereoscope	Stereoskop	A
062	Fusion and stereoscopic target	Perangkat untuk menampilkan hasil stereoskop	A
063	Nystagmus tape	Pita <i>nystagmus</i>	A
064	Spectacle dissociation test system	Sistem uji disosiasi kaca mata, seperti uji <i>Lancaster red-green</i>	A
065	Tonometer and accessories	Tonometer dan aksesoris	B
066	Transilluminator	Alat untuk mentransmisi cahaya pada pemeriksaan pasien	A
068	Ophthalmic Femtosecond Laser	Laser <i>Femtosecond</i>	C
069	Polymethylmethacrylate (Pmma) Diagnostic Contact Lens	Lensa kontak diagnostik PMMA yang ditujukan untuk diagnosis abnormalitas intraokular	C
070	Ophthalmodynamometer	Optalmodinamometer	C
071	Laser Scanning Ophthalmoscope	Optalmoskop yang menggunakan laser	B
072	Replacement Batteries Hand-Held Ophthalmoscopes	Baterai pengganti optalmoskop	A
073	Battery-Powered Thermal Soft-Lens Sterilizer ,	Mesin disinfeksi/sterilizer lensa kontak lunak berdaya baterai dengan metode termal	B
074	In-Office Tinting Contact Lenses System	Sistem pewarnaan lensa kontak	B
075	Implantable Miniature Telescope	Teleskop miniatur yang diimplan/ implan berukuran kecil yang diimplankan ke dalam lensa mata untuk	C

		memperbaiki penglihatan pada pasien <i>age-related macular degeneration</i> (AMD) stase akhir	
076	Optical Coherence Tomography	<i>Optical coherence tomography</i> (OCT)	B
077	Tonometer sterilizer	Alat sterilisasi tonometer	B
078	Retinal Diagnostic Software Device	Perangkat lunak diagnostik retina	C
079	Strabismus detection device	Alat deteksi strabismus	C
080	Diurnal pattern recorder system	Sistem perekam pola diurnal	C

## 12. Peralatan Mata

### 02. Peralatan Mata Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Ophthalmic tantalum clip	Alat penjepit pembuluh darah kecil di mata	C
002	Ophthalmic conformer	Alat penyangga ruang dalam rongga orbital	B
003	Artificial eye	Mata artifisial	A
004	Absorbable implant (scleral buckling method)	Implan yang dapat diserap (metode <i>scleral buckling</i> )	C
005	Eye sphere implant	Implan bola mata, <i>ocular peg</i>	C
006	Extraocular orbital implant	Implan orbital ekstraokular	C
007	Keratoprosthesis	Keratoprostesis	C
008	Intraocular lens	Lensa intraokular	D
009	Scleral shell	<i>Scleral shell</i>	B
010	Aqueous shunt	<i>Aqueous shunt</i>	C
011	Capsular tension ring	<i>Capsular tension ring</i> (CTR)/ Cincin tegangan kapsul	D

012	Sclera marker	Penanda sklera	B
013	Corneal storage media	Media penyimpan kornea	C
014	Endocapsular ring	Cincin endokapsular	C

## 12. Peralatan Mata

### 03. Peralatan Mata Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Powered corneal burr	Bor kornea elektrik	A
002	Radiofrequency electrosurgical cautery apparatus	Alat ESU <i>cautery</i> radiofrekuensi	C
003	Thermal cautery unit	Unit <i>cautery</i> termal	C
004	Vitreous aspiration and cutting instrument	Instrumen pemotong dan penghisap cairan <i>vitreous</i>	C
005	Cryophthalmic unit	Unit <i>cryophthalmic</i>	C
006	Ophthalmic knife test drum.	Alat penguji ketajaman pisau bedah mata	A
007	Intraocular gas	Gas intraokular	D
008	Intraocular fluid	Cairan intraokular	D
009	Intraocular pressure measuring device	Alat pengukur tekanan intraokuler	D
010	Intraocular lens guide	Alat pemasang lensa intraokuler	A
011	Operating headlamp	<i>Headlamp</i>	A
012	Manual ophthalmic surgical instrument	Instrumen bedah mata manual	A
013	Keratome	<i>Keratome</i>	A
014	Ophthalmic laser	Laser oftalmik	C
015	Nd:YAG laser for posterior capsulotomy and peripheral iridotomy	Laser Nd:YAG	C
016	Electronic metal locator	<i>Locator</i> logam elektrik	B
017	AC-powered magnet	Magnet elektrik	B
018	Permanent magnet	Magnet nonelektrik	A
019	Ophthalmic surgical marker	Alat penanda bedah mata	A

020	Ocular pressure applicator	Aplikator tekanan mata	B
021	Phacofragmentation system	Sistem fakofragmentasi/ <i>phacofragmentation</i>	C
022	Ophthalmic photocoagulator	Fotokoagulator oftalmik	C
023	Ophthalmic eye shield	Alat pelindung mata	A
024	Ophthalmic operating spectacles (loupes)	Kacamata operasi oftalmik ( <i>loupes</i> )	A
025	Ophthalmic sponge	Spons mata	B
026	Ophthalmic instrument table	Meja instrumen oftalmik	A
027	Ophthalmic excimer laser system	Sistem laser <i>excimer</i> mata	C
028	Excimer laser system	Sistem laser <i>excimer</i>	D
029	Intraocular Pressure Lowering Implant	Implan penurun tekanan intraokular	A
030	Fiberoptic Focusing Headlight	Lampu fokus serat optik	A
031	Tissue Adhesive For Ophthalmic Use	Perekat jaringan oftalmik	C
032	Corneal Refractive Implant	Implan refraktif kornea	C
033	Ophthalmic electrolysis unit	Alat elektrolisis oftalmik	B
034	Eye Valve Implant	Implan katup mata	C
035	Capsular Tension Ring Injector	Injektor Capsular tension rings (CTR)	C
036	Intraocular Pressure Lowering Implant	Implan penurun tekanan intraokular	C
037	Phacolysis LaserSystem	Laser fakolisis/ <i>phacolysis</i>	C
038	Punctum Plug	Alat oklusi sementara sistem drainase air mata	C
039	Absorbable Ophthalmic Suture	Benang bedah oftalmik yang dapat terabsorpsi	C
040	Nonabsorbable Ophthalmic Suture	Benang bedah oftalmik yang tidak dapat terabsorpsi	C
041	Ocular surgery irrigation device.	Perangkat irigasi operasi mata	B
042	Nasal Binacalicular Intubation	Intubasi <i>nasal binacalicular</i>	C
043	Scleral plug	<i>Scleral plug</i>	C
044	Corneal inlay inserter handle	Alat pemasang <i>corneal inlay</i>	A

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## 12. Peralatan Mata

### 04. Peralatan Mata Terapetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Ophthalmic beta radiation source	Sumber radiasi beta oftalmik	B
002	Low-power binocular loupe	Alat pembesar binokular berdaya rendah	A
003	Contact lens inserter/remover	Alat pemasang atau pelepas lensa kontak	A
004	Low-vision magnifier	Lensa pembesar	A
005	Ptosis crutch	Alat penahan kelopak mata <i>ptosis</i>	A
006	Ophthalmic bar reader	Alat bantu baca bentuk batang	A
007	Ophthalmic prism reader	Alat bantu baca bentuk prisma	A
008	Closed-circuit television reading system	Alat bantu baca bentuk televisi sirkuit tertutup	A
009	Magnifying spectacles	Kacamata pembesar	A
010	Prescription spectacle lens	Lensa kacamata resep	A
011	Low-vision telescope	Teleskop <i>low-vision</i>	A
012	Electronic vision aid	Alat bantu penglihatan elektronik	A
013	Image intensification vision aid	Alat bantu intensitas penglihatan	A
014	Optical vision aid.	Alat bantu penglihatan optik	A
015	Rigid gas permeable contact lens for extended wear	Lensa kontak permeabel gas yang kaku untuk penggunaan jangka panjang	D
016	Rigid gas permeable contact lens care products	Produk perawatan lensa kontak permeabel gas yang kaku	C
017	Soft (hydrophilic) contact lens	Lensa kontak lunak (hidrofilik)	C

018	Soft (hydrophilic) contact lens care products	Produk perawatan lensa kontak lunak (hidrofilik)	C
019	Rigid gas permeable contact lens for daily wear only	Lensa kontak permeabel gas yang kaku untuk penggunaan harian	C
021	Lacrimal stents and intubation sets	<i>Stent</i> lakrimal dan set intubasi	C
022	Contact lens for color vision deficiency	Lensa kontak untuk buta warna	C
023	Overnight contact lens orthokeratology	Lensa kontak ortokeratologi (ortho-K) untuk penggunaan <i>overnight</i>	C
024	Intraocular phakic Lens	Lensa intraokular <i>phakic</i>	D
025	Intraocular toric optics lens	Lensa intraokular <i>toric</i>	D
026	Iris reconstruction lens	Lensa rekonstruksi iris	D
027	Multifocal intraocular lens	Lensa intraokular multifokal	D
028	Intraocular accommodative lens	Lensa intraokular akomodasi	D
029	Specular microscope	Mikroskop <i>specular</i>	B
032	Soft (hydrophilic) contact lens (extended wear)	Lensa kontak lunak (hidrofilik) untuk pemakaian jangka panjang	D
035	Eyelid thermal pulsation system	Alat terapi kelopak mata termal berdaya elektrik	C
036	Tear electrostimulation device	Alat elektrostimulasi air mata	C
037	Intranasal electrostimulation device for dry eye symptoms	Alat elektrostimulasi intranasal untuk mata kering	C
038	Eyelid weight	Alat pemberat kelopak mata/ alat resep yang ditujukan untuk pengobatan lagophthalmos (penutupan kelopak mata yang tidak lengkap), bekerja dengan dibantu oleh gravitasi	C

039	Nasolacrimal compression device	Alat kompresi nasolakrimal	A
040	Oral electronic vision aid	Alat bantu penglihatan <i>deafblindness</i>	C

### 13. Peralatan Ortopedi

#### 01. Peralatan Ortopedi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Arthroscope	Artroskop	B
002	Nonpowered dynamometer	Dinamometer manual	A
003	AC-powered dynamometer	Dinamometer elektrik	B
004	Goniometer	Goniometer elektrik	B
005	Nonpowered goniometer	Goniometer manual	A

### 13. Peralatan Ortopedi

#### 02. Peralatan Ortopedi Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Bone fixation cerclage	Pengikat <i>cerclage</i> untuk fiksasi tulang	C
002	Bone heterograft	<i>Heterograft</i> tulang	D
003	Intramedullary fixation rod	Batang fiksasi untuk intramedular	C
004	Passive tendon prosthesis	Prostesis tendon pasif	C
005	Polymethylmethacrylate (PMMA) bone cement	Semen tulang polimetilmetakrilat (PMMA)	C
006	Single/multiple component metallic bone fixation appliances and accessories	Peralatan dan aksesoris untuk fiksasi tulang dengan kandungan logam tunggal/jamak	C
007	Smooth or threaded metallic bone fixation fastener	Pengencang fiksasi tulang	C
008	Resorbable calcium salt bone void filler device	Alat pengisi kekosongan tulang berbahan garam	C



		kalsium yang dapat diserap kembali	
009	Spinal interlaminar fixation orthosis	Ortosis fiksasi interlaminar tulang belakang	C
010	Spinal intervertebral body fixation orthosis	Ortosis fiksasi intervertebral tulang belakang	C
011	Thoracolumbosacral pedicle screw system	Sistem sekrup pedikel tulang belakang	C
012	Ankle joint metal/composite semi-constrained cemented prosthesis	Prostesis mengandung logam/komposit <i>semi-constrained cemented</i> pada sendi pergelangan kaki	C
013	Ankle joint metal/polymer semi-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>semi-constrained cemented</i> pada sendi pergelangan kaki	C
014	Ankle joint metal/polymer non-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>non-constrained cemented</i> pada sendi pergelangan kaki	D
015	Elbow joint metal/polymer constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>constrained cemented</i> pada sendi siku	C
016	Elbow joint metal/polymer semi-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>semi-constrained cemented</i> pada sendi siku	C
017	Elbow joint radial (hemi-elbow) polymer prosthesis	Prostesis mengandung polimer pada sendi siku radial ( <i>hemi-elbow</i> )	C
018	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	Prostesis mengandung logam <i>uncemented</i> pada sendi siku humeral ( <i>hemi-elbow</i> )	D
019	Finger joint metal/metal constrained uncemented prosthesis	Prostesis mengandung logam/logam <i>constrained</i>	D

		<i>cemented</i> pada sendi jari tangan	
020	Finger joint metal/metal constrained cemented prosthesis	Prostesis mengandung logam/logam <i>constrained cemented</i> pada sendi jari tangan	D
021	Finger joint metal/polymer constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>constrained cemented</i> pada sendi jari tangan	D
022	Finger joint polymer constrained prosthesis	Prostesis mengandung polimer <i>constrained</i> pada sendi jari tangan	C
023	Hip joint metal constrained cemented or uncemented prosthesis	Prostesis mengandung logam <i>constrained cemented</i> atau <i>uncemented</i> pada sendi pinggul	D
024	Hip joint metal/polymer constrained cemented or uncemented prosthesis	Prostesis mengandung logam/polimer <i>constrained cemented</i> atau <i>uncemented</i> pada sendi pinggul	C
025	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	Prostesis mengandung logam/logam <i>semi-constrained</i> , dengan komponen <i>acetabular cemented</i> pada sendi pinggul	D
026	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	Prostesis mengandung logam/logam <i>semi-constrained</i> , dengan komponen <i>acetabular uncemented</i> pada sendi pinggul	D
027	Hip joint metal/composite semi-constrained cemented prosthesis	Prostesis bahan logam/komposit <i>semi-constrained cemented</i> pada	C

		sendi pinggul	
028	Hip joint metal/polymer semi-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>semi-constrained cemented</i> pada sendi pinggul	C
029	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis	Prostesis mengandung logam/keramik/polimer <i>semi-constrained cemented</i> atau <i>nonporous uncemented</i> pada sendi pinggul	C
030	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis	Prostesis mengandung logam/polimer/logam <i>semi-constrained porous-coated uncemented</i> pada sendi pinggul	C
031	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis	Prostesis mengandung logam <i>cemented</i> atau <i>uncemented</i> pada sendi pinggul femoral ( <i>hemi-hip</i> )	C
032	Hip joint (hemi-hip) acetabular metal cemented prosthesis	Prostesis acetabular berbahan logam <i>cemented</i> pada sendi pinggul ( <i>hemi-hip</i> )	D
033	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	Prostesis trunnion-bearing berbahan logam/poliasetal <i>cemented</i> pada sendi pinggul femoral ( <i>hemi-hip</i> )	D
034	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis	Prostesis mengandung logam/polimer <i>cemented</i> atau <i>uncemented</i> pada sendi pinggul femoral ( <i>hemi-hip</i> )	C
035	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	Prostesis mengandung logam pengganti lapisan pada sendi pinggul femoral ( <i>hemi-hip</i> )	C
036	Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis	Prostesis mengandung logam/polimer atau keramik/polimer	D

		<i>semiconstrained cemented</i> pengganti lapisan pada sendi pinggul	
037	Knee joint femorotibial metallic constrained cemented prosthesis	Prostesis mengandung logam <i>constrained cemented</i> pada sendi lutut femorotibial	D
038	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	Prostesis mengandung logam/komposit <i>non-constrained cemented</i> pada sendi lutut femorotibial	C
039	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	Prostesis mengandung logam/komposit <i>semi-constrained cemented</i> pada sendi lutut femorotibial	C
040	Knee joint femorotibial metal/polymer constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>constrained cemented</i> pada sendi lutut femorotibial	C
041	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>non-constrained cemented</i> pada sendi lutut femorotibial	C
042	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>semi-constrained cemented</i> pada sendi lutut femorotibial	C
043	Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis	Prostesis mengandung logam/polimer <i>porous-coated uncemented</i> pada sendi lutut femorotibial ( <i>uni-compartmental</i> )	C
044	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>semi-constrained cemented</i> pada sendi lutut patelofemoral	C

045	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	Prostesis mengandung polimer/logam/logam <i>constrained cemented</i> pada sendi lutut patellofemorotibial	D
046	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	Prostesis mengandung polimer/logam/polimer <i>semi-constrained cemented</i> pada sendi lutut patellofemorotibial	C
047	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis	Prostesis mengandung logam/polimer <i>porous-coated uncemented</i> pada sendi lutut patellofemorotibial	C
048	Knee joint femoral (hemi-knee) metallic uncemented prosthesis	Prostesis mengandung logam <i>uncemented</i> pada sendi lutut femoralis ( <i>hemi-knee</i> )	D
049	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	Prostesis mengandung <i>uncemented</i> pengganti lapisan pada sendi lutut patela ( <i>hemi-knee</i> )	C
050	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	Prostesis mengandung logam <i>uncemented</i> pengganti lapisan pada sendi lutut tibialis ( <i>hemi-knee</i> )	C
051	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	Prostesis mengandung logam/logam atau logam/polimer <i>constrained cemented</i> pada sendi bahu	D
052	Shoulder joint metal/polymer non-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>non-constrained cemented</i> pada sendi bahu	C
053	Shoulder joint metal/polymer semi-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>semi-constrained cemented</i> pada sendi bahu	C

054	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis	Prostesis mengandung logam/polimer/logam <i>nonconstrained</i> atau <i>semi-constrained porous-coated uncemented</i> pada sendi bahu	C
055	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	Prostesis mengandung logam <i>cemented</i> pada <i>glenoid</i> sendi bahu ( <i>hemi-shoulder</i> )	D
056	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis	Prostesis mengandung logam <i>uncemented</i> pada humerus sendi bahu ( <i>hemi-shoulder</i> )	C
057	Toe joint polymer constrained prosthesis	Prostesis mengandung polimer <i>constrained</i> pada sendi jari kaki	C
058	Toe joint phalangeal (hemi-toe) polymer prosthesis	Prostesis mengandung polimer pada sendi jari kaki <i>phalangeal (hemi-toe)</i>	C
059	Wrist joint carpal lunate polymer prosthesis	Prostesis mengandung polimer pada sendi pergelangan tangan <i>carpal lunate</i>	C
060	Wrist joint carpal scaphoid polymer prosthesis	Prostesis mengandung polimer pada sendi pergelangan tangan <i>carpal scaphoid</i>	C
061	Wrist joint carpal trapezium polymer prosthesis	Prostesis mengandung polimer pada sendi pergelangan tangan <i>carpal trapezium</i>	C
062	Wrist joint polymer constrained prosthesis	Prostesis mengandung polimer <i>constrained</i> pada sendi pergelangan tangan	C
063	Wrist joint metal constrained cemented prosthesis	Prostesis mengandung logam <i>constrained cemented</i> pada	D

		sendi pergelangan tangan	
064	Wrist joint metal/polymer semi-constrained cemented prosthesis	Prostesis mengandung logam/polimer <i>semi-constrained cemented</i> pada sendi pergelangan tangan	C
065	Wrist joint ulnar (hemi-wrist) polymer prosthesis	Prostesis mengandung polimer pada sendi pergelangan tangan <i>ulnar (hemi-wrist)</i>	C
066	Intra articular fluid	Cairan intra artikular	D
067	Intervertebral body fusion device	Alat untuk menyatukan intervertebral	C
070	Intervertebral Disc Prosthesis,	Prostesis cakram intervertebral	D
072	Bone cap	<i>Bone cap</i>	A
073	In vivo cured intramedullary fixation rod	Batang fiksasi intramedular yang dibentuk secara in vivo	C

### 13. Peralatan Ortopedi

#### 03. Peralatan Ortopedi Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Orthopedic manual surgical instrument	Instrumen bedah ortopedi manual	A
002	Sonic surgical instrument and accessories/attachments	Instrumen bedah dengan frekuensi tinggi dan aksesoris	B
003	Protractor for clinical use	Protraktor medis	A
004	Template for clinical use	<i>Template</i> medis	A
005	Nonpowered orthopedic traction apparatus and accessories	Peralatan traksi ortopedi manual dan aksesoris	A

006	Noninvasive traction component	Komponen traksi noninvasif	A
007	Cast component	Komponen <i>cast</i>	A
008	Cast removal instrument	Instrumen elektrik untuk melepas <i>cast</i>	A
009	Manual cast application and removal instrument	Instrumen manual untuk memasang dan melepas <i>cast</i>	A
010	Calipers for clinical use	<i>Calipers</i> medis	A
011	Cement dispenser	Dispenser semen	A
012	Cement mixer for clinical use	Pengaduk semen medis	A
013	Cement monomer vapor evacuator	Evakuator uap monomer semen	A
014	Cement ventilation tube	Tabung ventilasi semen	A
015	Depth gauge for clinical use	<i>Gauge</i> medis	A
016	Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation	Instrumen bedah ortopedi untuk implan <i>osteochondral</i> dengan fiksasi <i>press-fit</i>	B

#### 14. Peralatan Kesehatan Fisik

##### 01. Peralatan Kesehatan Fisik Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Electrode cable	Kabel elektroda	B
002	Diagnostic electromyography	Elektromiograf (EMG)	B
003	Diagnostic electromyograph needle electrode	Elektroda elektromiograf	C
004	Powered reflex hammer	Palu refleks elektrik	B
005	Force-measuring platform	Alat ukur gaya	A
006	Intermittent pressure measurement system	Sistem ukur tekanan intermiten	A
007	Diagnostic muscle stimulator	Alat diagnosa stimulasi otot	B
008	Isokinetic testing and evaluation system	Sistem uji isokinetik	B
009	Muscle monitoring device	Alat monitor otot	B
010	EMG-triggered powered exercise equipment	Alat latihan <i>EMG-Triggered</i> elektrik	B



011	Chronaximeter	Kronaksimeter	B
012	Miniature pressure transducer	Miniatur transduser tekanan	A

#### 14. Peralatan Kesehatan Fisik

##### 02. Peralatan Kesehatan Fisik Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Prosthetic and orthotic accessory	Penunjang ortosis dan prosthesis	A
002	External limb orthotic component	Komponen ortosis eksternal anggota gerak	A
003	External limb prosthetic component	Komponen prosthesis eksternal anggota gerak	A
004	Limb orthosis	Ortosis anggota gerak	A
005	Truncal orthosis	Ortosis badan	A
006	External assembled lower limb prosthesis	Prosthesis eksternal rakitan untuk anggota gerak bawah	B
007	Arm sling	Mitela, penyangga tangan	A
008	Denis Brown splint	<i>Denis Brown splint</i>	A
009	Powered wheeled stretcher	Tandu elektrik beroda	B
010	Nonpowered communication system	Sistem komunikasi non-elektrik	A
011	Powered communication system	Sistem komunikasi elektrik	B
012	Powered environmental control system	Sistem kontrol lingkungan (elektrik)	B
013	Cane, crutch, and walker tips and pads	Bantalan tongkat, kruk, dan alat bantu jalan	A
014	Mechanical walker	Alat bantu jalan mekanik	A
015	Special grade wheelchair	Kursi roda khusus	B
016	Standup wheelchair	Kursi roda berdiri	B
017	Wheelchair elevator	Elevator kursi roda	B
018	Wheelchair platform scale	Kursi roda dengan timbangan	A
019	Intraarticular hyaluronic acid	Injeksi cairan lutut asam hyaluronat	D
020	Transfer aid	Alat bantu pindah pasien	A
021	Finger-sucking device	Alat pencegah hisap-jari	A

022	Cane	Tongkat	A
023	Mechanical chair	Kursi mekanis	A
024	Electric positioning chair	Kursi posisi elektrik	B
025	Crutch	Kruk	A
026	Flotation cushion	Bantal tiup	A
027	Plinth	Alas periksa	A
028	Rigid pneumatic structure orthosis	Ortosis tulang pnuematik <i>rigid</i>	C
029	Congenital hip dislocation abduction splint	<i>Splint</i> abduksi dislokasi kongenital	A
030	Mechanical table	Meja mekanik	A
031	Powered table	Meja elektrik	B
032	Motorized three-wheeled vehicle	Kursi beroda tiga bermotor	B
033	Mechanical wheelchair	Kursi roda mekanis	A
034	Powered wheelchair	Kursi roda elektrik	B
035	Stair-climbing wheelchair	Kursi roda untuk menaiki tangga	C
036	Powered lower extremity exoskeleton	Eksoskeleton anggota gerak bagian bawah elektrik	B
037	Upper extremity prosthesis including simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical componennts	Prostesis anggota gerak bagian atas elektrik non-implan	B

#### 14. Peralatan Kesehatan Fisik

##### 03. Peralatan Kesehatan Fisik Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Daily activity assist device	Alat bantu aktivitas harian	A
002	Nonpowered sitz bath	Baskom <i>sitz</i> non-elektrik	A
003	Powered patient transport	Tandu pasien elektrik	B

004	Air-fluidized bed	Kasur udara terfluidasi	B
005	Powered flotation therapy bed	Kasur terapi apung elektrik	B
006	Manual patient rotation bed	Kasur rotasi pasien manual	A
007	Powered patient rotation bed	Kasur rotasi pasien elektrik	B
008	Moist steam cabinet	Alat sauna	B
009	Microwave diathermy	Diatermi gelombang mikro	B
010	Shortwave diathermy	Diatermi gelombang pendek	B
011	Ultrasonic diathermy	Diatermi ultrasonik	B
012	Exercise component	Alat latihan fisik medis	A
013	Measuring exercise equipment	Alat latihan fisik medis dengan alat ukur	B
014	Nonmeasuring exercise equipment	Alat latihan fisik medis tanpa alat ukur	A
015	Powered finger exerciser	Alat latihan jari elektrik	A
016	Infrared lamp	Lampu infra merah	B
017	Iontophoresis device	Alat <i>iontophoresis</i>	B
018	Powered external limb overload warning device	Alat peringatan penggunaan anggota gerak eksternal elektrik	B
019	Powered inflatable tube massager	Alat pijat dengan tekanan udara elektrik	B
020	Therapeutic massager	Alat terapi pijat	A
021	Cold pack	Kompres dingin	A
022	Hot or cold disposable pack	Kompres panas atau dingin sekali pakai	A
023	Water circulating hot or cold pack	Kompres panas atau dingin dengan sirkulasi air	B
024	Moist heat pack	Kompres panas lembab	A
025	Powered heating pad	Bantalan pemanas elektrik	B
026	Presssure-applying device	Alat terapi dengan tekanan	A
027	Powered muscle stimulator	Stimulator otot elektrik	B
028	Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions	Stimulator otot dan gelombang ultrasound untuk mengurangi nyeri, kaku otot, dan nyeri sendi	B
029	Ultrasound and muscle stimulator for	Stimulator otot dan	C

	all other uses	gelombang ultrasound selain untuk mengurangi nyeri, kaku otot, dan nyeri sendi	
030	Multi-function physical therapy table	Meja terapi fisik multifungsi	B
031	Power traction equipment	Alat traksi elektrik	B
032	Traction accessory	Aksesoris traksi	A
033	Chilling unit	Unit pendingin	A
034	Powered heating unit.	Unit pemanas elektrik	A
035	Therapeutic vibrator	Vibrator terapi	A
036	Pressure-applying electric device	Alat terapi dengan tekanan elektrik	B
037	Dry heat fluidized therapy	Terapi panas kering terfluidasi	B
038	Extracorporeal shock wave treatment	Alat terapi ekstrakorporeal gelombang kejut	D
039	Plunger-like joint manipulator	Manipulator sendi <i>plunger-like</i>	A
040	Spine curvature monitor	Monitor lengkungan tulang belakang	B
041	Peripheral electromagnetic field (PEMF) to aid wound healing	Peripheral electromagnetic field (PEMF) untuk penyembuhan luka	D
042	Immersion hydrobath	Bak air perendam	C
043	Paraffin bath	Bak paraffin	B
044	Powered exercise equipment	Alat latihan elektrik	B
045	Internal therapeutic massager	Alat pijat terapi internal (transvaginal dan transrektal) untuk <i>chronic pelvic pain syndromes</i>	C
046	Nonpowered lower extremity pressure wrap	Alat pemberi tekanan pada bagian kaki non-elektrik	A

## 15. Peralatan Radiologi

### 01. Peralatan Radiologi Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Magnetic resonance diagnostic device	MRI	C

002	Bone densitometer	Densitometer tulang	C
003	Emission computed tomography system	Tomografi emisi	C
004	Fluorescent scanner	<i>Scanner fluoresensi</i>	B
005	Nuclear tomography system	Tomografi nuklir	C
006	Radionuclide dose calibrator	Kalibrator dosis radionuklida	B
007	Nuclear anthropomorphic phantom	<i>Phantom anthropomorphic nuklir</i>	A
008	Nuclear flood source phantom	<i>Phantom sumber muatan nuklir</i>	A
009	Radionuclide rebreathing system	<i>Rebreathing radionuclide system</i>	B
010	Radionuclide test pattern phantom	<i>Phantom penguji pola radionuklida</i>	A
011	Nonfetal ultrasonic monitor	Monitor ultrasonik nonfetus	B
012	Ultrasonic pulsed doppler imaging system	<i>Doppler ultrasound / USG</i>	B
013	Ultrasonic pulsed echo imaging system	<i>USG echo</i>	B
014	Diagnostic ultrasonic transducer	Transduser / probe (USG, pembuluh darah, jaringan)	B
015	Angiographic X-ray system	Angiografi; <i>Cathlab</i>	C
016	Diagnostic X-ray beam-limiting device	Kolimator	C
017	Cine or spot fluorographic X-ray camera	Kamera sinar X fluorografi	C
018	Electrostatic X-ray imaging system	Mesin sinar X elektrostatik	C
019	Radiographic film marking system	<i>Film marking system</i>	A
020	Image-intensified fluoroscopic X-ray system	<i>Image intensified fluoroscopic</i> (dengan tabung penguat sinar); pesawat sinar X, <i>fluoroscopy</i>	C
021	Non-image-intensified fluoroscopic X-ray system	<i>Non image fluoroscopic</i> (tanpa tabung penguat sinar )	C
022	Spot-film device	<i>Spot film / alat penangkap cahaya</i>	C

023	Stationary X-ray system	Sinar X konvensional; <i>fixed table X-ray system; general X-ray</i> ; pesawat rontgen untuk penggunaan umum	C
024	Mammographic X-ray system	Mamografi sinar X	C
025	Mobile X-ray system	<i>Mobile X-ray</i>	C
026	Photofluorographic X-ray system	Sistem fotofluorografik sinar X	C
027	Tomographic X-ray system	Tomografi sinar X	C
028	Computed tomography X-ray system	<i>CT Scan</i>	C
029	Pneumoencephalographic chair	Kursi <i>Pneumoencephalographic</i>	C
030	Radiologic patient cradle	Alat fiksasi pasien radioterapi	A
031	Radiographic film	Film rontgen	A
032	Radiographic film cassette	Kaset film rontgen	B
033	Radiographic film/cassette changer	Alat pengganti kaset / film rontgen	B
034	Radiographic film/cassette changer programmer	Program pengganti kaset / film rontgen	B
035	Wall-mounted radiographic cassette holder	Kaset <i>holder</i>	A
036	Radiographic film illuminator	Illuminator film radiografi	A
037	Automatic radiographic film processor	Prosesor film rontgen otomatis	B
038	Radiographic grid	<i>Grid</i> radiografi	A
039	Radiographic head holder	Penyangga kepala radiografi	A
040	Radiologic quality assurance instrument	Instrumen penjamin kualitas radiologi	A
041	Radiographic anthropomorphic phantom	<i>Phantom anthropomorphic</i>	A
042	Radiographic intensifying screen	Layar penguat sinar X	A
043	Radiologic table	Meja radiologi	B
044	Transilluminator for breast evaluation	Transiluminator untuk payudara	D
045	Medical image storage device	Tempat penyimpanan film	A

046	Medical image communications device	Alat komunikasi gambar medis	A
047	Medical image digitizer	<i>Digitizer</i> hasil sinar X	B
048	Medical image hardcopy device	Pencetak film sinar X	B
049	Picture archiving and communications system	PACS	B
050	Bone Sonometer	Sonometer tulang	C
051	High Intensity Focused Ultrasound (HIFU) Mr-Guided ablation system	Sistem pemandu ablasi HIFU	D
052	Medical linear accelerator	LINAC ( <i>Linear Accelerator</i> )	C
053	Medical Image Analyzer	Alat CADe (computer-assisted/aided detection)	D
054	Radiographic Aperture	<i>Aperture</i> radiografi	B
055	Hyperthermia deep heating ultrasound applicator	Aplikator ultrasound untuk <i>hyperthermia</i>	D
056	Interstitial hyperthermia applicator	Aplikator <i>hyperthermia interstitial</i>	D
057	Superficial hyperthermia Rf/microwave applicator	Aplikator gelombang mikro untuk <i>hyperthermia superficial</i>	D
058	Biopsy needle guide kit	Kit jarum biopsi	B
059	Focal spot radiographic camera	<i>Focal spot</i> kamera radiologi	C
060	Multi format radiological camera	Kamera radiologi multi format	B
061	Cooling cap infants	Pelindung kepala bayi untuk tindakan radiologi	D
062	Chest X-ray computer aided detection	<i>CAD chest X-ray</i>	B
063	Digital breast tomosynthesis	<i>Digital breast tomosynthesis</i>	D
064	Implanted ionizing radiation dosimeter	Dosimeter radiasi tanam	C
065	Full-field digital mammography system	Sistem mamografi digital	C
066	Hydrogel spacer	<i>Hydrogel spacer</i>	B
067	Electrical impedance breast imager	Alat pencitraan impedansi payudara	D
068	Barium enema disposable kit	Kit enema barium	B

069	Solid state X-ray imager (flat panel/digital imager)	Panel penerima hasil sinar X	B
070	Scintillation (gamma) camera	Kamera gamma	B
071	Positron camera	Kamera positron	B
072	Nuclear whole body counter	Alat pengukur jumlah paparan nuklir	B
073	Nuclear uptake probe	Probe nuklir	B
074	Nuclear whole body scanner	Alat pemindai paparan nuklir	B
075	Nuclear sealed calibration source	Alat kalibrasi keamanan nuklir	B
076	Scintillation (gamma) camera	Kamera gamma	B
077	Positron camera	Kamera positron	B
078	Nuclear electrocardiograph synchronizer	EKG nuklir <i>synchronizer</i>	B
079	Diagnostic X-ray high voltage generator	Generator sinar X	C
080	Diagnostic X-ray tube housing assembly	Wadah tabung sinar X	C
081	Diagnostic x-ray tube mount.	Penyangga tabung sinar X	C
082	Radiographic ECG/respirator synchronizer	<i>Radiographic ECG/respirator synchronizer</i>	B
083	Radiological Computer Assisted Detection And Diagnosis for lessions suspicious of cancer	CAD Software untuk lesi kanker	C
084	Radiological computer aided triage and notification software (terdapat pada CFR)	Software radiologi untuk triase	C

## 15. Peralatan Radiologi

### 02. Peralatan Radiologi Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Medical charged-particle radiation therapy system	Terapi partikel radiasi	C
002	Medical neutron radiation therapy	Radioterapi neutron medis	C



	system		
003	Remote controlled radionuclide applicator system	Aplikator radionuklida otomatis	C
004	Radiation therapy beam-shaping block	<i>Radiation therapy beam-shaping block</i>	B
005	Radionuclide brachytherapy source	Sumber radionuklida untuk brakhiterapi	C
006	Radionuclide radiation therapy system	Radioterapi radionuklida	D
007	Powered radiation therapy patient support assembly	Alat penunjang terapi radiasi	B
008	Radiation therapy simulation system	Simulator radioterapi	B
009	X-ray radiation therapy system	Radioterapi sinar X	C
010	Therapeutic x-ray tube housing assembly	Wadah tabung sinar X	C
011	High intensity focused ultrasound	Alat terapi <i>ultrasound</i> intensitas tinggi	D
012	Cancer treatment hyperthermia system (with Rf/microwave)	Sistem terapi hipertermia untuk kanker (dengan <i>Rf/microwave</i> )	C
013	Manual radionuclide applicator system	Aplikator radionuklida manual	B
014	Radionuclide teletherapy source	Sumber teleterapi radionuklida	C
015	Light beam patient position indicator	Indikator posisi pasien untuk paparan sinar radiasi	B
016	Rectal balloon for prostate immobilization	Balon rektal untuk immobilisasi prostat pada terapi radiasi	C
017	Absorbable perirectal spacer	<i>Perirectal spacer</i>	C
018	Bladder cancer treatment hyperthermia system (with chemotherapy)	Sistem terapi hipertermia untuk kanker kandung kemih (dengan kemoterapi)	D

15. Peralatan Radiologi

03. Peralatan Radiologi Lainnya

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Personnel protective shield	Apron, <i>clothing</i> , furnitur, dan alat pelindung radiasi baik statis maupun dinamis	A

16. Peralatan Bedah Umum dan Bedah Plastik

01. Peralatan Bedah Diagnostik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Volume sizer for breast implant	Pengukur volume implan payudara	B
002	Speculum and accessories	Spekulum dan aksesoris	A

16. Peralatan Bedah Umum dan Bedah Plastik

02. Peralatan Bedah Prostetik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	External facial fracture fixation appliance	Alat fiksasi fraktur wajah eksternal	A
002	Surgical mesh	<i>Mesh</i> bedah	B
003	Polytetrafluoroethylene with carbon fibers composite implant material	Material implan PTFE dengan serat karbon	C
004	Silicone inflatable breast prosthesis	Payudara prostesis <i>inflatable</i> silikon	D
005	Silicone gel-filled breast prosthesis	Payudara prostesis berisi gel silikon	D
006	Chin prosthesis	Dagu prostesis	C
007	Ear prosthesis	Telinga prostesis	C
008	Esophageal prosthesis	Esofagus prostesis	C
009	Nose prosthesis	Hidung prostesis	C
010	Tracheal prosthesis	Trakea prostesis	C
011	External aesthetic restoration prosthesis	Restorasi prostesis estetika eksternal	A
012	Inflatable extremity splint	<i>Inflatable extremity splint</i>	A

013	Noninflatable extremity splint	<i>Noninflatable extremity splint</i>	A
014	Plastic surgery kit and accessories	Kit bedah plastik dan aksesoris	A
015	Dermal filler	<i>Dermal filler</i>	D
016	External prosthesis adhesive	Perekat protesis eksternal	C

## 16. Peralatan Bedah Umum dan Bedah Plastik

### 03. Peralatan Bedah

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Hydrophilic wound dressing	Pembalut luka hidrofilik	A
002	Occlusive wound dressing	Pembalut luka oklusif	A
003	Hydrogel wound dressing and burn dressing	Dressing hidrogel dan dressing untuk luka bakar	B
004	Silicone sheeting	Lembaran silikon	A
005	Surgical apparel	Masker medis, masker bedah, <i>cover-all</i> , surgical gown	B
006	Surgical apparel other than surgical gowns and surgical masks	<i>Shoe cover, cap, medical goggles</i>	A
007	Organ bag	Kantong organ	B
008	Surgical camera and accessories	Kamera bedah dan aksesoris	A
009	Removable skin clip	Klip kulit dapat dilepas	B
010	Cryosurgical unit and accessories	Unit <i>cryosurgical</i> dan aksesoris	C
011	Surgical drape and drape accessories	Duk bolong dan aksesoris	B
012	Drape adhesive	Perekat duk	A
013	Electrosurgical cutting and coagulation device and accessories.	ESU dan aksesoris	C
014	Low energy ultrasound wound cleaner	Pembersih luka <i>ultrasound</i> tenaga rendah	B
015	Eye pad	Pad mata / penutup mata	A
016	Surgeon's glove	Sarung tangan bedah	A
017	Surgeon's gloving cream	Krim sarung tangan bedah	A
018	Absorbable powder for lubricating a surgeon's glove	Serbuk <i>absorbable</i> untuk lubrikasi sarung tangan bedah	D
019	Absorbable hemostatic agent and dressing	Bahan dan <i>dressing</i> hemostatik <i>absorbable</i>	D

020	Absorbable poly(glycolide/ 1-lactide) surgical suture	Benang bedah poli (glikolid / l-lactat) <i>absorbable</i>	C
021	Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology	Benang bedah poli (hidroksibutirat) <i>absorbable</i> yang diproduksi dengan teknologi DNA rekombinan	C
022	Stainless steel suture	Benang bedah <i>stainless steel</i>	C
023	Polytetrafluoroethylene injectable	Injeksi politetrafluoroetilen	D
024	Surgical lamp	Lampu bedah, lampu operasi	B
025	Ultraviolet lamp for dermatologic disorders	Lampu ultraviolet untuk kelainan kulit	B
026	Ultraviolet lamp for tanning	Lampu ultraviolet untuk <i>tanning</i>	B
027	Skin marker	<i>Marker</i> kulit	A
028	Surgical microscope and accessories	Mikroskop bedah dan aksesoris	A
029	Surgical skin degreaser or adhesive tape solvent	<i>Degreaser</i> kulit bedah atau pelarut pita perekat	A
030	Implantable staple	Staples implan	C
031	Powered suction pump	Pompa <i>suction</i> elektrik	B
032	Manual surgical instrument for general use	Instrumen bedah umum	A
033	Laser surgical instrument for use in general and plastic surgery and in dermatology	Instrumen laser bedah umum, bedah plastik dan dermatologi	C
034	Absorbable surgical gut suture	Benang bedah <i>gut</i> yang dapat diserap	C
035	Absorbable polydioxanone surgical suture	Benang bedah polidioksanon <i>absorbable</i>	C
036	Suture retention device	Benang bedah retensi	A
037	Manual operating table and accessories and manual operating chair and accessories	Meja dan kursi operasi manual dan aksesoris	A
038	Nonabsorbable poly(ethylene terephthalate) surgical suture	Benang bedah poli(etilen tereftalat) non <i>absorbable</i>	C
039	Nonabsorbable polypropylene	Benang bedah polipropilen	C

	surgical suture	<i>non absorbable</i>	
040	Nonabsorbable polyamide surgical suture	Benang bedah poliamid non <i>absorbable</i>	C
041	Natural nonabsorbable silk surgical suture	Benang bedah sutra alami non <i>absorbable</i>	C
042	Nonabsorbable expanded polytetrafluoroethylene surgical suture	Benang bedah polytetrafluoroethylene <i>expanded non absorbable</i>	C
043	Suction lipoplasty system	Sistem lipoplasti <i>suction</i>	C
044	Tissue adhesive for the topical approximation of skin	Perekat jaringan untuk topikal	C
045	Tissue adhesive for non-topical use	Perekat jaringan untuk non-topikal	D
046	Contact cooling system for aesthetic use	Sistem pendingin kontak untuk penggunaan estetika	C
047	Bone wax	Lilin tulang	B
048	Wound Irrigation Solution	Larutan irigasi luka	B
049	Shockwave generator for pain relief	Generator <i>shockwave</i> untuk meringankan nyeri	D
050	Introduction/drainage catheter and accessories	Kateter drainase dan aksesoris	B
051	Nonabsorbable gauze for internal use	Kasa, spons untuk penggunaan internal	A
052	Removable skin staple	Staples kulit yang dapat dilepas	B
053	Surgical instrument motors and accessories/attachments	Instrumen motor bedah dan aksesoris	B
054	Wound Irrigation Solution	Larutan irigasi luka	B
055	Implantable Clip	Klip yang dapat diimplan	C
056	Nonresorbable gauze/sponge for external use, sterile	Kasa, spons steril untuk penggunaan eksternal	A
057	Nonresorbable gauze/sponge for external use, non sterile	Kasa, spons non steril untuk penggunaan eksternal	A
058	Introduction/drainage catheter and	Kateter drainase dan aksesoris	B

	accessories		
059	Adhesion barrier	<i>Adhesion barrier</i>	D
060	Focused ultrasound stimulator system for aesthetic use	Sistem stimulator <i>ultrasound</i> terfokus untuk penggunaan estetika	B
061	Surgical sealant	<i>Sealant</i> bedah	D
062	Operating tables and accessories with modification	Meja operasi dan aksesori dengan modifikasi	B
063	Absorbable lung biopsy plug	<i>Plug</i> untuk biopsi paru yang <i>absorbable</i>	C
064	Sunlamp products and ultraviolet lamps intended for use in sunlamp products	Produk <i>sunlamp</i> dan lampu ultraviolet untuk penggunaan <i>sunlamp</i>	B
065	Microneedling device for aesthetic use	Alat <i>microneedling</i> untuk penggunaan estetika	C
066	Electrosurgical device for over-the-counter aesthetic use	ESU OTC untuk penggunaan estetika	C
067	Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia	Sistem pendingin kulit kepala untuk mengurangi <i>alopecia</i> akibat kemoterapi	C
068	Adhesion barrier	<i>Adhesion barrier</i>	D
069	Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive	<i>Dressing</i> dengan aditif <i>poly (diallyl dimethyl ammonium chloride) (pDADMAC)</i>	C
070	Drug wound dressing	<i>Dressing</i> mengandung obat	D
071	Non-Powered suction apparatus device intended for negative pressure wound therapy	Perangkat alat penghisap tanpa daya yang ditujukan untuk terapi luka tekanan negatif	C
072	Ultrasonic surgical instrument	Peralatan bedah ultrasonik	B
073	Antiseptic wound dressing	<i>Dressing</i> antiseptik	C
074	Hemostatic dressing	<i>Dressing</i> hemostatik	C
075	Non-absorbable hemostatic gauze for temporary internal use	<i>Gauze</i> hemostatik yang tidak dapat diserap untuk penggunaan internal	C

		sementara	
076	Nonabsorbable expandable hemostatic sponge for temporary internal use	Spons hemostatik yang tidak dapat diserap untuk penggunaan internal sementara	C
077	Wound autofluorescence imaging device	Alat pencitraan autofluoresensi pada luka	A
078	Irrigating wound retractor device	Alat retraktor irigasi luka	C
079	Internal tissue marker	Penanda jaringan internal	C
080	Powered surgical instrument for improvement in the appearance of cellulite	Instrumen bedah untuk memperbaiki tampilan selulit (elektrik)	C
081	Magnetic surgical instrument system	Sistem instrumen bedah magnetik	C
082	Light based energy source device for topical application	Alat sumber energi berbasis cahaya untuk aplikasi topikal	C
083	Surgical smoke precipitator	Evakuator asap bedah	C
084	Tissue adhesive with adjunct wound closure device for topical approximation of skin	Perekat jaringan dengan tambahan alat penanda luka	C
085	Hemostatic device for intraluminal gastrointestinal use	Alat hemostatik untuk penggunaan gastrointestinal intraluminal	C

## 16. Peralatan Bedah Umum dan Bedah Plastik

### 04. Peralatan Bedah Terapeutik

Kode	Jenis Produk	Penamaan (Sinonim)	Kelas Risiko
001	Air-handling apparatus for a surgical operating room	Alat pengatur udara untuk ruang operasi	B
002	Needle-type epilator	Jarum <i>epilator</i>	A
003	Tweezer-type epilator	<i>Tweezer epilator</i>	A
004	Topical oxygen chamber for extremities	<i>Chamber</i> oksigen topikal untuk ektrimitas	C
005	Nonpneumatic tourniquet	<i>Nonpneumatic tourniquet</i>	A

006	Synthetic absorbable suture	Benang bedah sintesis dapat diserap	C
007	Pneumatic tourniquet	<i>Pneumatic tourniquet</i>	B
008	Low level laser systems for aesthetic use	Sistem laser tingkat rendah untuk penggunaan estetika	C
009	Air-handling apparatus accessory	Alat penunjang untuk pengatur udara medis	A


MENTERI KESEHATAN  
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ttd.

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