



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 8011
Faksimile : (021) 52964838 Kotak Pos : 203



Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

ALAT KESEHATAN

KEMENKES RI AKL 10504026033

Nama Dagang / Merek : **ASANUS PRO Basic Cardiovascular Set**
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A
Kategori Produk : Peralatan Kardiologi
Sub Kategori : Peralatan Kardiologi Bedah
Jenis Produk : Cardiovascular surgical instruments.
Tipe / Ukuran : Terlampir
Kemasan : Plastik, Dus
Nama Produsen / Pabrikan : ASANUS MEDIZINTECHNIK GMBH, Germany
Nama Pendaftar : PT. ASANUS MEDIKA INDONESIA, Banten
Atas dasar lisensi dari : -

Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 01 Juli 2025.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 09 Oktober 2020



Catatan:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
- Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



LAMPIRAN

**NOMOR IZIN EDAR
ALAT KESEHATAN
KEMENKES RI AKL 10504026033**

No.	Deskripsi	Tipe / Kode
1	"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL0470
2	"Backhaus" towel clamp 90 mm, 3 1/2" total length	PRO-KL0740
3	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
4	Scalpel handle No.3, str. ,mirror finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
5	Scalpel handle No.3, str. ,mirror finsh. for blades fig. 10-15, 40, 42 210 mm, 8 1/4" total length	PRO-SK0427
6	"Mayo" dissecting scissors bl./bl., str., tip 3,5 mm 170 mm, 6 3/4" total length	PRO-SC1932
7	Dissecting scissors a. Mayo, curved, 155 mm 6 1/8" total length	PRO-SC1941
8	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
9	"Metzenbaum" dissecting scissor bl./bl., cur., tip 3,1 mm 200 mm, 8" total length	PRO-SC2307
10	"Nelson-Metzenbaum" dissecting scissors bl./bl., cur., tip 4,0 mm 230 mm, 9 1/8" total length	PRO-SC2309
11	"Kelly" fistula scissors sh./sh., curved, 25 mm blade 175 mm, 7" total length	PRO-SC0591
12	"Potts-Smith" micro vascular scissors sh./sh., 25° angled, 190 mm 7 1/2" total length	PRO-SC2650
13	"Potts-Smith" scissors sh./sh., 45° angled, 185 mm 7 1/4" total length	PRO-SC2660
14	Universal wire scissors soft bis Ø 1,2 mm, hard bis Ø 0,6 mm 120 mm, 5" total length	PRO-DZ0199
15	"Adson" anatomic forceps str., tip 1,5 mm, serrated, flat handle 120 mm, 4 3/4" total length	PRO-PZ0560
16	"Adson-Brown" surgical forceps str., tip 2,2 mm, 9x9 teeth, flat handle 120 mm, 4 3/4" total length	PRO-PZ1640
17	"Cushing" anatomic forceps str., tip 1,2 mm, serrated, fl handle 180 mm, 7 1/8" total length	PRO-PZ0640
18	"DeBakey" atr. forceps, straight Safety-Pin and press stoper, tip 2,0 mm 200 mm, 8" total length	PRO-GF0760
19	"DeBakey" atr. forceps, straight safety-pin with press-stopper, tip 2,0 m 240 mm, 9 1/2" total length	PRO-GF0780
20	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 155 mm, 6 1/8" total length	PRO-PZ1269
21	"Allis" intestinal grasping forceps straight, tip 5,3 mm, 5x6 teeth 155 mm, 6 1/8" total length	PRO-MD0130
22	"Allis" intestinal grasping forceps straight, tip 5,7 mm, 5x6 teeth 190 mm, 7 1/2" total length	PRO-MD0140

Lampiran 1 dari 3 Halaman



Catatan:

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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
23	"Allis-Adair"intest.-/tissue gras. forc. mouth 10,5 mm, 10x11 teeth 155 mm, 6 1/8" total length	PRO-MD0104
24	Surgical forceps, russian model str, ring-Ø 6,0 mm, serrated, flat handl 150 mm, 6" total length	PRO-PZ1710
25	Surgical forceps, russian model str, ring-Ø 7,0 mm, serrated, flat handl 200 mm, 8" total length	PRO-PZ1720
26	"Babcock" intestinal grasping forceps straight, tip 8,0 mm, serrated jaw 155 mm, 6 1/8" total length	PRO-MD0210
27	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230
28	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
29	"Crile" haemostatic forceps straight, tip 1,6 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2390
30	"Crile" haemostatic forceps curved, tip 1,6 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2391
31	"Rochester-Pean" haemostatic forceps curved, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3085
32	"Rochester-Carmalt" haemostatic forceps straight, tip 2,5 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3352
33	"Kocher-Ochsner" haemostatic forceps str., tip 2,7mm,1x2 teeth, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3320
34	"Mixer" dissect./ligature forceps curved, tip 2,3 mm, serrated jaw 180 mm, 7 1/8" total length	PRO-KL4338
35	"Craford" haemostatic forceps curved,tip 2,5 mm,serrated jaw,delicate 185 mm, 7 1/4" total length	PRO-KL2781
36	"Crafoord" haemostatic forceps curved, tip 3,2 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL2780
37	"Heiss" haemostatic forceps curved, tip 2,1 mm, serrated jaw 200 mm, 8" total length	PRO-KL2641
38	"Senn-Miller" retractor, double ended 8x7 mm (3-teeth sh.) & 18x5,5 mm hooks 160 mm, 6 1/4" total length	PRO-WH0130
39	Woundretractor Fino 4 prongs sharp 210 mm, 8 1/4" long, 8,5 x 9,5mm	PRO-WH0978
40	"Weitlaner" self-retaining retractor sharp, 3/4 teeth 135 mm, 5 1/8" total length	PRO-WH5190
41	Vulva retractor Gelpi 30 mm depth, sharp prongs 180 mm, 7 1/8" long	PRO-WH6981
42	"Cushing" vein retractor with fenestrated handle	PRO-WH0139
43	"Parker" retractor, double ended 1 set, 24x23 / 26x23mm, 27x25 / 29x24mm 180 mm, 7 1/8" total length	PRO-WH0211
44	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
45	"Deaver" retractor fig.1, 25 mm wide 300 mm, 12" total length	PRO-WH2540
46	"Deaver" retractor fig.3, 38 mm wide 300 mm, 12" total length	PRO-WH2560
47	"Deaver" retractor fig.4, 50 mm wide 310 mm, 12 1/4" total length	PRO-WH2570
48	"Deaver" retractor fig.5, 75 mm wide 320 mm, 12 3/4" total length	PRO-WH2600

Lampiran 2 dari 3 Halaman



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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
49	"Richardson" retractor blunt, blade 23x20 mm 240 mm, 9 1/2" total length	PRO-WH2090
50	"Richardson" retractor blunt, blade 30x29 mm 240 mm, 9 1/2" total length	PRO-WH2100
51	"Richardson" retractor blunt, blade 37x37 mm 240 mm, 9 1/2" total length	PRO-WH2110
52	"Richardson" retractor blunt, blade 47x21 mm 240 mm, 9 1/2" total length	PRO-WH2120
53	Wound hook "Green", 28X20 mm, 225 mm	PRO-WH1820
54	Abdominal/intestinal spatula blade 30 mm wide, malleable 330 mm, 13 1/8" total length	PRO-WH3110
55	Abdominal/intestinal spatula blade 40 mm wide, malleable 330 mm, 13 1/8" total length	PRO-WH3120
56	Abdominal/intestinal spatula blade 50 mm wide, malleable 330 mm, 13 1/8" total length	PRO-WH3130
57	"Krayenbuehl" vessel hook small, with ball tip 185 mm, 7 1/4" total length	PRO-MN1910
58	"Krayenbuehl" vessel hook large, with ball tip 185 mm, 7 1/4" total length	PRO-MN1920
59	"Pool" suction hose Ø-tip 8 mm (23Fr.) 225 mm, 9" total length	PRO-SG0620
60	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
61	"Frazier" suction tube, angled Charriere 10, Ø 3 mm 130 mm, 5 1/8" total length	PRO-SG0181
62	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
63	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
64	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
65	Crile-Wood needle holder delicate 180 mm 7 1/8" total length, Daily-Line	PRO-ENH1182
66	"Lebsche" sternum chisel 250 mm, 10" total length	PRO-GF3630
67	"Bergmann" mallet Ø 45 mm, 500 g 245 mm, 9 3/4" total length	PRO-KN2130
68	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
69	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
70	Teflon long time filter for max.2000 cycles Ø 194 mm	PRO-ZB9094

Dengan ketentuan bahwa izin edar tersebut hanya berlaku untuk deskripsi dan tipe / kode produk yang tercantum dalam lampiran ini

Jakarta, 09 Oktober 2020



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Rx ONLY

GA-01



Basic Cardiovascular Set

LP: 04-09-04/0

1 pcs.

REF PRO-KL0740

LOT 20064795

06.09.2018



"Backhaus" towel clamp 90 mm, 3 1/2" total length

(01)04060414086553

(10)20064795

Date: 14.10.2019

Cust.-No.: 13098 ID ASANUS INDONESIA/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....

Diproduksi oleh :

ASANUS Medizintechnik GmbH, Neuhausen - Germany

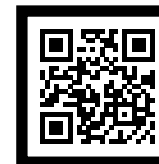
Diimpor oleh :

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AUF: 20192065/40



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GA-01



Basic Cardiovascular Set

LP: 04-03-13/6

1 pcs.

REF PRO-SK0426

LOT 20030084



15.11.2018



(01)04060414184198

(10)20030084

Date: 14.10.2019

Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

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AUF: 20192065/10



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GA-01



Basic Cardiovascular Set

LP: 14-03-05/2

1 pcs.

REF PRO-SC2305

LOT 21802447

26.06.2018



(01)04060414171334

(10)21802447

Date: 14.10.2019

"Metzenbaum" dissecting scissors bl./bl.,
cur., tip 2,8 mm 180 mm, 7 1/8" total length

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....

Diproduksi oleh :

ASANUS Medizintechnik GmbH, Neuhausen - Germany

Diimpor oleh :

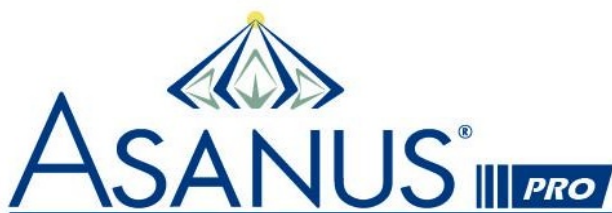
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/20



ASANUS Medizintechnik GmbH, take-off Gewerbepark 2, D-78579 Neuhausen ob Eck, info@asanus.de





www.asanus.de



R_X ONLY

GA-01



Basic Cardiovascular Set

LP: 05-02-11/6

1 pcs.

REF PRO-PZ0560

LOT 21803269



29.08.2018



"Adson" anatomic forceps str., tip 1,5 mm, serrated, flat handle 120 mm, 4 3/4" total length

(01)04060414159349

(10)21803269

Date: 14.10.2019

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....

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Diimpor oleh :

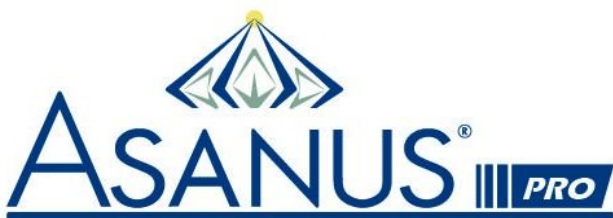
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AUF: 20192065/30



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Rx ONLY

GA-01



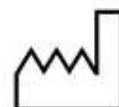
Basic Cardiovascular Set

LP: 03-05-14/4

1 pcs.

REF PRO-WH0320

LOT 21901853



13.05.2019



(01)04060414210095

(10)21901853

Date: 15.10.2019

"US-Army" retractor, double ended 1 set,
22x15 / 39x15mm, 26x15 / 43x15mm 220
mm, 8 3/4" total length

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....

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AUF: 20192065/80



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Rx ONLY

GA-01



Basic Cardiovascular Set

LP: 08-03-05/5

1 pcs.

REF PRO-MN1910

LOT 21901531

24.04.2019



"Krayenbuehl" vessel hook small, with ball tip
185 mm, 7 1/4" total length

(01)04060414203707

(10)21901531

Date: 15.10.2019

Cust.-No.: 13098 ID ASANUS INDONESIA/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....

Diproduksi oleh :

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AUF: 20192065/130



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Rx ONLY

GA-01



Basic Cardiovascular Set

LP: 02-06-13/7

1 pcs.

REF PRO-SG0840

LOT 21800225

19.01.2018



"Yankauer" suction tube curved, Ø 10 mm
275 mm, 11" total length

(01)04060414181975

(10)21800225

Date: 15.10.2019

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....

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AUF: 20192065/160



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GA-01



Basic Cardiovascular Set

LP: 02-03-11/2

1 pcs.

REF PRO-NH1230

LOT 21605437



28.09.2016



"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length

(01)04060414139372

(10)21605437

Date: 14.10.2019

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....

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AUF: 20192065/50



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GA-01



Basic Cardiovascular Set

LP: 01-09-06/3

1 pcs.

REF PRO-GF3630

LOT 20121547

10.11.2018



"Lebsche" sternum chisel 250 mm, 10" total length

(01)04060414098716

(10)20121547

Date: 15.10.2019

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

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Diimpor oleh :

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AUF: 20192065/220



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GA-01



Basic Cardiovascular Set

LP: 02-03-06/9

1 pcs.

REF PRO-KN2130

LOT 21902105

03.06.2019



"Bergmann" mallet Ø 45 mm, 500 g 245 mm,
9 3/4" total length

(01)04060414096736

(10)21902105

Date: 15.10.2019

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

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AUF: 20192065/140



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GA-01



Basic Cardiovascular Set

LP: 01-05-10/4

1 pcs.

REF PRO-CE5703S

LOT 20170156

23.02.2017



(01)04060414064988

(10)20091865

Date: 15.10.2019

Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

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AUF: 20192065/100



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Rx ONLY

GA-01



Basic Cardiovascular Set

LP: 08-03-05/5

1 pcs.

REF PRO-ST5783

LOT 20190853

24.04.2019



(01)04060414203707

(10)21901531

Date: 15.10.2019

Wire basket 1/1, full size, with fall handle
480x250x100 mm

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

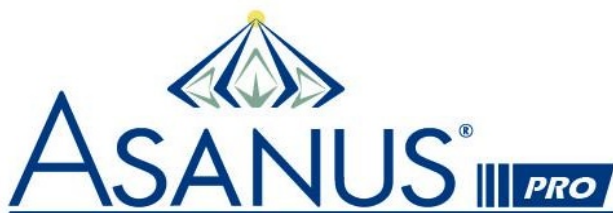
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AUF: 20192065/130



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GA-01



Basic Cardiovascular Set

LP: 03-07-09/3

1 pcs.

REF PRO-ZB9094

LOT 20185294

24.02.2018



Teflon long time filter for max.2000 cycles Ø 194 mm

(01)04060414156768

(10)20140356

Date: 15.10.2019

Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

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AUF: 20192065/150



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