



**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 11603026723

Nama Dagang / Merek : **ASANUS PRO Thoracotomy Instrument set**
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A
Kategori Produk : Peralatan Bedah Umum dan Bedah Plastik
Sub Kategori : Peralatan Bedah
Jenis Produk : Manual surgical instrument for general use.
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, 08 November 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.

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LAMPIRAN

**NOMOR IZIN EDAR
ALAT KESEHATAN
KEMENKES RI AKL 11603026723**

No.	Deskripsi	Tipe / Kode
1	"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, surrated 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. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
5	Scalpel handle No.3, str. ,mirrow 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	Power TC universal scissors soft bis Ø 1,2 mm, hard bis Ø 0,8 mm 120 mm, 5" total length	PRO-DZ0200
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 4 Halaman



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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	"Pean" tubing and artery clamp surrated jaw, mouth 4,8 mm 145 mm, 5 3/4" total length	PRO-DG1820
36	"Crafoord" haemostatic forceps curved,tip 2,5 mm,serrated jaw,delicate 185 mm, 7 1/4" total length	PRO-KL2781
37	"Crafoord" haemostatic forceps curved, tip 3,2 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL2780
38	"Heiss" haemostatic forceps curved, tip 2,1 mm, serrated jaw 200 mm, 8" total length	PRO-KL2641
39	"Senn-Miller" retractor, double ended 8x7 mm (3-teeth sh.) & 18x5,5 mm hooks 160 mm, 6 1/4" total length	PRO-WH0130
40	Woundretractor Fino 4 prongs sharp 210 mm, 8 1/4" long, 8,5 x 9,5mm	PRO-WH0978
41	"Weitlaner" self-retaining retractor sharp, 3/4 teeth 135 mm, 5 1/8" total length	PRO-WH5190
42	Vulva retractor Gelpi 30 mm depth, sharp prongs 180 mm, 7 1/8" long	PRO-WH6981
43	"Cushing" vein retractor with fenestrated handle	PRO-WH0139
44	"Parker" retractor, double ended 1 set, 24x23 / 26x23mm, 27x25 / 29x24mm 180 mm, 7 1/8" total length	PRO-WH0211
45	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
46	"Deaver" retractor fig.1, 25 mm wide 300 mm, 12" total length	PRO-WH2540
47	"Deaver" retractor fig.3, 38 mm wide 300 mm, 12" total length	PRO-WH2560

Lampiran 2 dari 4 Halaman



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No.	Deskripsi	Type / Kode
48	"Deaver" retractor fig.4, 50 mm wide 310 mm, 12 1/4" total length	PRO-WH2570
49	"Deaver" retractor fig.5, 75 mm wide 320 mm, 12 3/4" total length	PRO-WH2600
50	"Richardson" retractor blunt, blade 23x20 mm 240 mm, 9 1/2" total length	PRO-WH2090
51	"Richardson" retractor blunt, blade 30x29 mm 240 mm, 9 1/2" total length	PRO-WH2100
52	"Richardson" retractor blunt, blade 37x37 mm 240 mm, 9 1/2" total length	PRO-WH2110
53	"Richardson" retractor blunt, blade 47x21 mm 240 mm, 9 1/2" total length	PRO-WH2120
54	Wound hook "Green", 28X20 mm, 225 mm	PRO-WH1820
55	Abdominal/intestinal spatula blade 30 mm wide, malleable 330 mm, 13 1/8" total length	PRO-WH3110
56	Abdominal/intestinal spatula blade 40 mm wide, malleable 330 mm, 13 1/8" total length	PRO-WH3120
57	Abdominal/intestinal spatula blade 50 mm wide, malleable 330 mm, 13 1/8" total length	PRO-WH3130
58	"Krayenbuehl" vessel hook small, with ball tip 185 mm, 7 1/4" total length	PRO-MN1910
59	"Krayenbuehl" vessel hook large, with ball tip 185 mm, 7 1/4" total length	PRO-MN1920
60	"DeBakey-Derra" atr. baby anast. clamp large 170 mm, 6 3/4" total length	PRO-GF2060
61	"DeBakey-Derra" atr. baby anast. clamp middle 170 mm, 6 3/4" total length	PRO-GF2050
62	"DeBakey-Satinsky" atr vascular clamp fig.3, branche backw. cur., doub. ang. 250 mm, 10" total length	PRO-GF1672
63	Atrauma anastomosis clamp "Glover" curved, 220 mm 8 3/4" long	PRO-GF1166
64	"DeBakey" atraumatic aorta clamp shaft backw. cur., cur, tip 3,5 mm 265 mm, 10 1/2" total length	PRO-GF1410
65	"Leland-Jones" atr. peripheral-clamp branche backw. cur., 60° ang, tip 2,3 mm 185 mm, 7 1/4" total length	PRO-GF1300
66	"DeBakey-Satinsky" atr vascular clamp branche backw. curved, doub. angled 240 mm, 9 1/2" total length	PRO-GF1630
67	"DeBakey" atr. baby vas. multipurpose cl 30° angle 165 mm, 6 1/2" total length	PRO-GF2080
68	"DeBakey" atr. baby vas. multipurpose cl 60° angle 160 mm, 6 1/4" total length	PRO-GF2090
69	"DeBakey" atr. baby vas. multipurpose cl 90° angle 150 mm, 6" total length	PRO-GF2100
70	"Baby-Finocchio"rib retractor,st. steel blades 18x20 mm, spreading 85 mm 130 mm, 5 1/8" total length	PRO-GF3290
71	"Sarot" power TC needle holder straight, tip 2,0 mm, needle size 4-6 mm 180 mm, 7 1/8" total length	PRO-NH0270
72	"Alexander" raspatory double-edged 210 mm, 8 1/4" total length	PRO-KN1190
73	"Doyen" raspatory, for adults curved to right, 30x25 mm 175 mm, 7" total length	PRO-KN1160

Lampiran 3 dari 4 Halaman



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No.	Deskripsi	Tipe / Kode
74	"Doyen" raspatory, for adults curved to left, 30x25 mm 175 mm, 7" total length	PRO-KN1150
75	"Bailey" rib contractor 215 mm, 8 1/2" total length	PRO-GF3330
76	"Davidson" shoulderretractor 89x83 mm 195mm, 7 3/4" total length	PRO-WH2390
77	"Finochietto" rib retractor blades 46x65 mm, spreading 200 mm 305 mm, 12 1/8" total length	PRO-GF3080
78	"Finochietto" rib retractor blades 70x65 mm, spreading 250 mm 355 mm, 14 1/8" total length	PRO-GF3090
79	"Pool" suction hose Ø-tip 8 mm (23Fr.) 225 mm, 9" total length	PRO-SG0620
80	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
81	"Frazier" suction tube, angled Charriere 10, Ø 3 mm 130 mm, 5 1/8" total length	PRO-SG0181
82	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
83	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
84	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
85	"Lebsche" sternum chisel 250 mm, 10" total length	PRO-GF3630
86	"Bergmann" mallet Ø 45 mm, 500 g 245 mm, 9 3/4" total length	PRO-KN2130
87	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
88	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
89	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, 08 November 2020

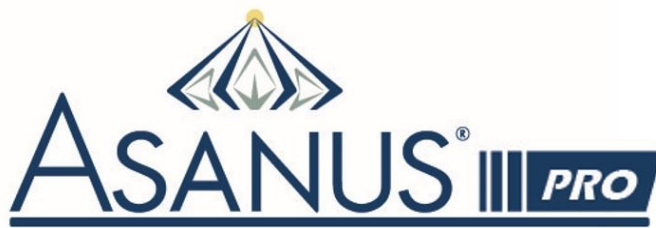


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GA-01



THORACOTOMY SET

LP: 04-09-04/0

1 pcs.

REF PRO-KL0760

LOT 20064795

06.09.2018



"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length

(01)04060414086553

(10)20064795

Date: 14.10.2019

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: 20192065/40



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





www.asanus.de



GA-01



THORACOTOMY SET

LP: 14-03-05/2

1 pcs.

REF PRO-SK0426

LOT 21802447

26.06.2018



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

(01)04060414171334

(10)21802447

Date: 14.10.2019

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

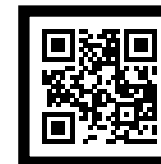
Your order no.: sample labels, 14.10.2019

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Diproduksi oleh :
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany
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PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/20



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GA-01



THORACOTOMY SET

LP: 05-02-11/6

1 pcs.

REF PRO-PZ1640

LOT 21803269



29.08.2018



"Adson-Brown" surgical forceps str., tip 2,2 mm, 9x9 teeth, 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

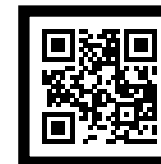
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AUF: 20192065/30



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Rx ONLY

GA-01



THORACOTOMY SET

LP: 03-05-14/4

1 pcs.

REF PRO-SC1932

LOT 21901853



"Mayo" dissecting scissors bl./bl., str., tip 3,5 mm 170 mm, 6 3/4" total length

13.05.2019

(01)04060414210095

(10)21901853

Date: 15.10.2019

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

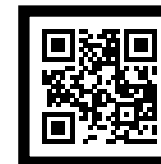
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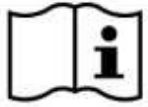
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Diproduksi oleh :
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Diimport oleh :
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/80



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GA01



THORACOTOMY SET
LP: 05-11-03/8

1 pcs.

REF PRO-NH1240

LOT 21901493



Needle holder a. Hegar - Mayo droite, 185mm 185 mm,
7 1/4" total length

23.04.2019

(01)04060414179705
(10)21901493

Date: 15.10.2019

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

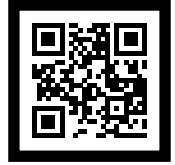
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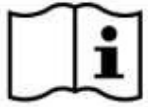
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AUF: 20192065/70



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GA01



THORACOTOMY SET
LP: 05-11-03/8

1 pcs.

REF PRO-WH0320

LOT 21901493



23.04.2019



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

(01)04060414179705

(10)21901493

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

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Diproduksi oleh :
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PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/70



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GA-01



THORACOTOMY SET

LP: 02-06-13/7

1 pcs.

REF PRO-KN2130

LOT 21800225



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

19.01.2018

(01)04060414181975

(10)21800225

Date: 15.10.2019

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

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AUF: 20192065/160



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GA-01



THORACOTOMY SET

LP: 01-05-10/4

1 pcs.

REF PRO-CE5703S

LOT 20170156

23.02.2017



(01)04060414064988
(10)20091865

Date: 15.10.2019

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

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AUF: 20192065/100



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GA-01



THORACOTOMY SET

LP: 08-03-05/5

1 pcs.

REF PRO-ST5783

LOT 20190853

24.04.2019



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

(01)04060414203707

(10)21901531

Date: 15.10.2019

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

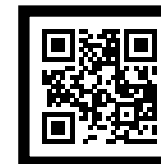
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Diimpor oleh :
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AUF: 20192065/130



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





www.asanus.de



GA-01



THORACOTOMY 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

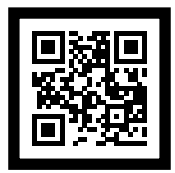
Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....
Diproduksi oleh :
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany
Diimpor oleh :
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/150



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





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GA-01; GA-14



THORACOTOMY SET

LP: 14-02-04/4

1 pcs.

REF PRO-KL2231

LOT 21900041



11.01.2019



"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length

(01)04060414121087

(10)21900041

Date: 15.10.2019

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 :

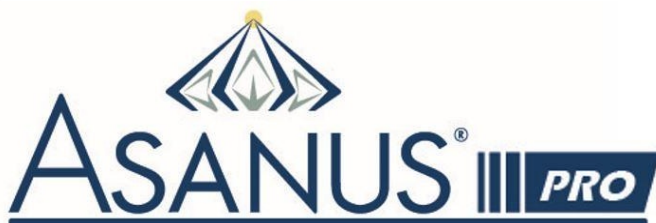
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/260



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Rx ONLY

GA-01



THORACOTOMY SET

LP: A02D504

1 pcs.

REF PRO-SG0840

LOT 21900094



14.01.2019



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

(01)04060414118025

(10)21900094

Date: 15.10.2019

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

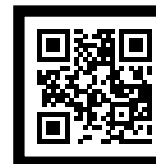
Diimpor oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/250



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





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Rx ONLY

GA-01



1 pcs.

THORACOTOMY SET
LP: 03-07-09/3

REF PRO-GF3630

LOT 20140356

24.02.2018



(01)04060414156768
(10)20140356

Date: 15.10.2019

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: 20192065/150



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