



**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 11002026034**

Nama Dagang / Merek : **ASANUS PRO Laminectomy Set**  
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A  
Kategori Produk : Peralatan Neurologi  
Sub Kategori : Peralatan Neurologi Bedah  
Jenis Produk : Nonpowered neurosurgical instrument.  
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 11002026034**

No.	Deskripsi	Tipe / Kode
1	Scalpel handle No.7, mirror finsh. for blades fig. 10-15, 40, 42 160 mm, 6 1/4" total length	PRO-SK0428
2	Scalpel handle No.4, short for blades fig. 18-36 135 mm, 5 1/4" total length	PRO-SK0432
3	"Deaver" surgical scissors sh./bl., straight, 145 mm 5 3/4" total length	PRO-SC1650
4	"Mayo" dissecting scissors bl./bl., str., tip 3,5 mm 170 mm, 6 3/4" total length	PRO-SC1932
5	Dissecting scissors a. Mayo, curved, 155 mm 6 1/8" total length	PRO-SC1941
6	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
7	Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0204
8	Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 8" total length	PRO-PZ0270
9	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
10	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 200 mm, 8" total length	PRO-PZ1290
11	"Cushing" anatomic forceps str., tip 1,5 mm, serrated, fl handle 175 mm, 7" total length	PRO-PZ0586
12	"Cushing" surgical forceps str., tip 2,0 mm, 1x2 teeth, flat handle 175 mm, 7" total length	PRO-PZ1672
13	"Taylor" anat.forceps, bayo.shaped hand. str., tip 1,6 mm, with scraper 175 mm, 7" total length	PRO-PZ0344
14	"Taylor" surgical forceps,bayonet-shaped str., tip 1,6mm, 1x2 teeth, w. guide pin 175 mm, 7" total length	PRO-PZ1678
15	"Frazier" suction tube, angled Charriere 10, Ø 3 mm 130 mm, 5 1/8" total length	PRO-SG0181
16	"Frazier" suction tube Charriere 12, 4,0mm diameter 125 mm, 5" working length	PRO-SG0182
17	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
18	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230
19	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
20	"Crile" haemostatic forceps, curved 1X2 teeth, 160 mm, 6 1/4" total length	PRO-KL2550
21	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
22	"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL0470

Lampiran 1 dari 3 Halaman



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23	"Cushing" vein retractor with fenestrated handle	PRO-WH0139
24	"Volkman" retractor 4 teeth, 8x19 mm, blunt 220 mm, 8 3/4" total length	PRO-WH1200
25	"WEITLANER" WOUNDRTRACTOR, SHARP 3X4 TEETH, 200 MM, 8" TOTAL LENGTH	PRO-WH5380
26	Beckmann woundretractor with 4x4 sharp prongs 300 mm, 12" total length	PRO-WH5367
27	Dissector"Langenbeck" 8mm width, 200mm, 8" total length	PRO-KN0410
28	Langenbeck periosteal elevator narrow 10 mm, 195mm 7 3/4" total length	PRO-KN0420
29	"Cushing" raspatory 15,0 mm wide 195 mm, 7 3/4" total length	PRO-KN0911
30	"Bergmann" mallet Ø 45 mm, 500 g 245 mm, 9 3/4" total length	PRO-KN2130
31	"Bruns" bone curette fig. 000, straight, mouth 2 mm 230 mm, 9 1/8" total length	PRO-KN1651
32	"Bruns" bone curette fig. 00, straight, mouth 2,5 mm 230 mm, 9 1/8" total length	PRO-KN1652
33	"Bruns" bone curette fig. 0, straight, mouth 3 mm 230 mm, 9 1/8" total length	PRO-KN1653
34	"Williger" bone curette fig. 2, round, mouth 6 mm 170 mm, 6 3/4" total length	PRO-KN1648
35	"Caspar" rongeur 150° angled upwards, mouth 12x3 mm 160 mm, 6 1/4" length of shaft	PRO-WS0160
36	"Davis" dissector curved, double ended, 245 mm, 9 3/4", total length	PRO-MN3550
37	"Chusing" micro and suture hook, large ball tip, 2,6 mm neck, round 190 mm, 7 1/2" total length	PRO-WH0370
38	"Love" micro root hook bayonett angled 210 mm 8 1/4" total length	PRO-MN3221
39	"Luer" bone rongeur straight 175 mm, 7" total length	PRO-KN4840
40	"Luer-Stille" bone rongeur curved, 9,5x15 mm jaw 225 mm, 9" total length	PRO-KN5060
41	"Stille" bone rongeur lateral curved 220 mm, 8 3/4" total length	PRO-KN5020
42	"Leksell-Stille" bone rongeur lateral curved, mouth bite 22,0 mm 240 mm, 9 1/2" total length	PRO-KN5030
43	Retractor "Caspar" with hook PRO-WH7072 and 5 blades PRO-WH7075- PRO-WH7079	PRO-WH7070
44	Retractor "Caspar" only	PRO-WH7071
45	Screw driver alone for spreader PRO-WH7070	PRO-WH7071-1
46	Hook only, 38 mm with 80° bending, blunt	PRO-WH7072
47	Blades only, 37 X 22 mm with 80° blunt	PRO-WH7075
48	Blades only, 42 X 22 mm with 90° blunt	PRO-WH7076
49	Blades only, 47 X 22 mm with 80° blunt	PRO-WH7077
50	Blades only, 52 X 22 mm with 80° blunt	PRO-WH7078
51	Blade only, 57 X 22 mm with 80° angle blunt	PRO-WH7079
52	"Easy-Line"Kerrison bone punch,detach. 130°cutt.upw.,bite 1mm,thin footpl. 200 mm, 8" length of shaft	PRO-MN5321F
53	"Easy-Line"Kerrison bone punch,detach. 130°cut.up.,bite 2mm, thin footpl.ecj 200 mm, 8" length of shaft	PRO-MN5322FA

Lampiran 2 dari 3 Halaman



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No.	Deskripsi	Tipe / Kode
54	"Easy-Line"Kerrison bone punch,detach. 130°cutt.upw.,bite 3mm,thin footpl.ecj. 200 mm, 8" length of shaft	PRO-MN5323FA
55	"Easy-Line"Kerrison bone punch,detach. 130°cutt.upw.,bite 4mm,thin footpl.ecj. 200 mm, 8" length of shaft	PRO-MN5324FA
56	"Easy-Line"Kerrison bone punch,detach. 130°cutt.upw.,bite 5mm,thin footpl.ecj. 200 mm, 8" length of shaft	PRO-MN5325FA
57	"Easy-Line"Kerrison bone punch,detach. 130°cutt.upw.,bite 6mm,thin footpl.ecj. 200 mm, 8" length of shaft	PRO-MN5326FA
58	"Love-Gruenwald" rongeur 150° angled downwards, mouth 10x3 mm 180 mm, 7 1/8" length of shaft	PRO-MN4570
59	"Penfield" dissector curved, double ended, 6,7/6,5 mm 175 mm, 7" total length	PRO-MN3500
60	"Penfield" dissector curved, double ended, 6,6/3,8 mm 195 mm, 7 3/4" total length	PRO-MN3510
61	Hemilaminectomy retractor Scoville- Haverfield complete	PRO-WH5540
62	Frame alone for PRO-WH5540	PRO-WH5550
63	Hook "Scoville", 55 mm, for PRO-WH5540 soldered	PRO-WH5560
64	"Scoville" blade, 63X25 mm, for PRO-WH5540	PRO-WH5570
65	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
66	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
67	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

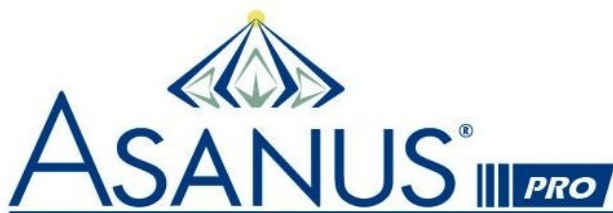


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GA-01



1 pcs.

LAMINECTOMY SET

LP: 04-09-04/0

**REF** PRO-SK0428

**LOT** 20064795

06.09.2018



(01)04060414086553

(10)20064795

**Date: 14.10.2019**

Scalpel handle No.7, mirror finish. for blades fig. 10-15, 40, 42 160 mm, 6 1/4" 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 :

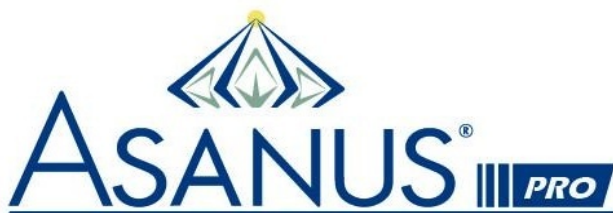
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**AUF: 20192065/40**



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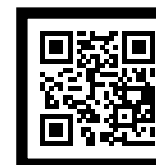
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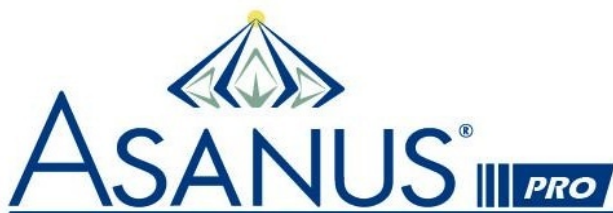
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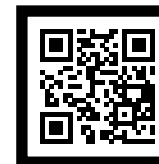
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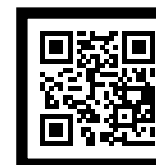
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GA-01



LAMINECTOMY SET

LP: 04-03-13/6

1 pcs.

REF PRO-SC1650

LOT 20030084



15.11.2018



"Deaver" surgical scissors sh./bl., straight, 145 mm 5 3/4" total length

(01)04060414184198

(10)20030084

Date: 14.10.2019

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

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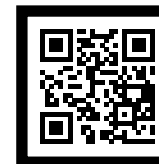
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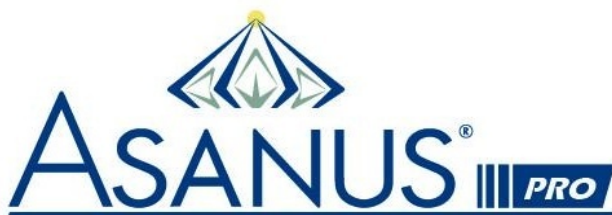
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AUF: 20192065/10



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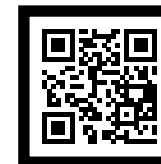
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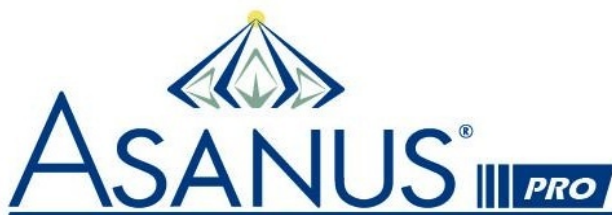
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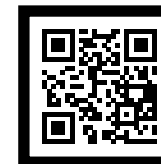
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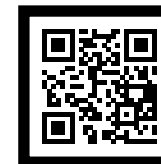
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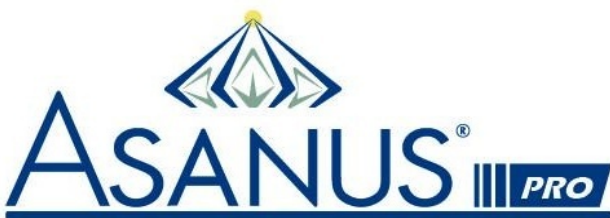
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GA-01



LAMINECTOMY SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-SC2305

**LOT** 21802447

26.06.2018



"Metzenbaum" dissecting scissors bl./bl.,  
cur., tip 2,8 mm 180 mm, 7 1/8" 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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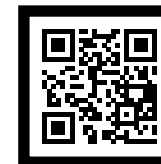
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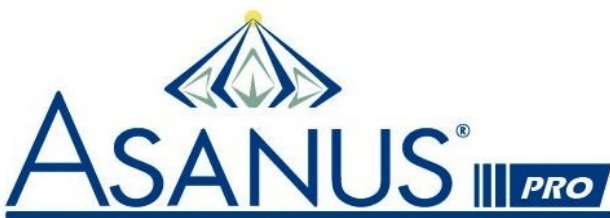
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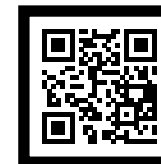
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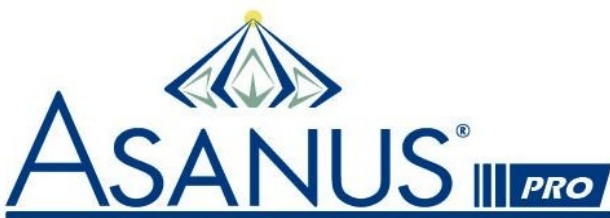
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AUF: 20192065/20



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Rx ONLY

GA-01



LAMINECTOMY SET

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26.06.2018



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

KEMENKES RI AKL.....

Diproduksi oleh :

ASANUS Medizintechnik GmbH, Neuhausen - Germany

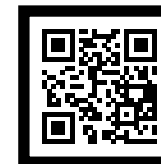
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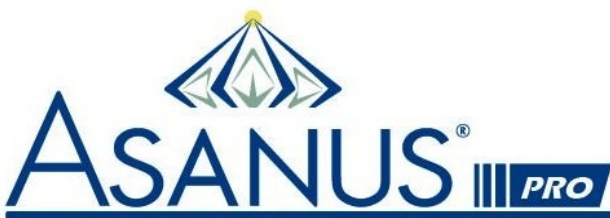
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/20



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





www.asanus.de



GA-01



LAMINECTOMY SET

LP: 14-03-05/2

1 pcs.

REF PRO-SC2305

LOT 21802447

26.06.2018



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

KEMENKES RI AKL.....

Diproduksi oleh :

ASANUS Medizintechnik GmbH, Neuhausen - Germany

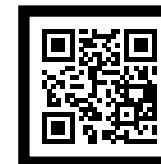
Diimpor oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/20



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







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Rx ONLY

GA-01



1 pcs.

LAMINECTOMY SET

LP: 05-02-11/6

REF PRO-PZ1672

LOT 21803269



29.08.2018



"Cushing" surgical forceps str., tip 2,0 mm, 1x2 teeth, flat handle 175 mm, 7" 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.....

Diproduksi oleh :

ASANUS Medizintechnik GmbH, Neuhausen - Germany

Diimpor oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/30



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

