



**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 11002026722**

Nama Dagang / Merek : **ASANUS PRO Basic Neurosurgery 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, 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.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



LAMPIRAN

**NOMOR IZIN EDAR  
ALAT KESEHATAN  
KEMENKES RI AKL 11002026722**

No.	Deskripsi	Tipe / Kode
1	Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
2	Scalpel handle No.4, short for blades fig. 18-36 135 mm, 5 1/4" total length	PRO-SK0432
3	Scalpel handle No.4L for blades fig. 18-36 215 mm, 8 1/2" total length	PRO-SK0433
4	Power TC surgical scissors, sh./bl., straight, 145 mm 5 3/4" total length	PRO-SC0870
5	"Mayo" dissecting scissors bl./bl., str., tip 3,5 mm 170 mm, 6 3/4" total length	PRO-SC1932
6	Dissecting scissors a. Mayo, curved, 155 mm 6 1/8" total length	PRO-SC1941
7	"Toennis" dissecting scissors bl./bl., curved, 180 mm 7 1/8" total length	PRO-SC2560
8	Anatomic tissue forceps str., tip 2,6 mm, serrated, flat handle 180 mm, 7 1/8" total length	PRO-PZ0160
9	"Treves" surgical forceps str., tip 2,5 mm, 1x2 teeth, flat handle 150 mm, 6" total length	PRO-PZ1719
10	"Semken" anatomic forceps, delicate str., tip 1,0 mm, serrated, flat handle 150 mm, 6" total length	PRO-PZ0530
11	"McIndoe" anatomic forceps str., tip 0,8 mm, serrated, fl handle 150 mm, 6" total length	PRO-PZ0630
12	"Gillies" surgical forceps str, tip 1,5mm,1x2 teeth, cross serrated 150 mm, 6" total length	PRO-PZ1460
13	"Waugh" surgical forceps str, tip 2,5mm,1x2 teeth, cross serrated 200 mm, 8" total length	PRO-PZ1570
14	"Cushing" anatomic forceps str., tip 1,5 mm, serrated, fl handle 175 mm, 7" total length	PRO-PZ0586
15	"Gerald" anatomic forceps straight, tip 1,0 mm, serrated 175 mm, 7" total length	PRO-PZ0580
16	"Gerald" surgical forceps str., tip 1,4 mm, 1x2 teeth, flat handle 175 mm, 7" total length	PRO-PZ1480
17	"Stille-Barraya" sur. vessel forceps str, tip 3,3mm,3x4 teeth, cross serrated 200 mm, 8" total length	PRO-PZ1670
18	"Gruenwald" forceps, bayonet-shaped str., tip 2,0 mm, serrated, flat handle 200 mm, 8" total length	PRO-PZ1910
19	Double ended probe tip Ø 1,5 mm 145 mm, 5 3/4" total length	PRO-SD0400
20	Double ended probe tip Ø 2,0 mm 145 mm, 5 3/4" total length	PRO-SD0450
21	Probes straight 200 mm, 8" total length	PRO-SD0122
22	"Nelaton" probe curved, bluntt 160 mm, 6 1/4" total length	PRO-SD0140
23	"Frazier" suction tube, angled Charriere 10, Ø 3 mm 130 mm, 5 1/8" total length	PRO-SG0181
24	"Frazier" suction tube Charriere 12, 4,0mm diameter 125 mm, 5" working length	PRO-SG0182

Lampiran 1 dari 3 Halaman



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 BSrE.



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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
25	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
26	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
27	"Crile-Wood" power TC needle holder straight, tip 2,2 mm, needle size 4-6 mm 200 mm, 8" total length	PRO-NH0260
28	"Deschamp" ligature needle for right hand, blunt 210 mm, 8 1/4" total length	PRO-ND2380
29	"Deschamp" ligature needle for left hand, blunt 210 mm, 8 1/4" total length	PRO-ND2390
30	"Micro-Halsted" haemostatic forceps straight, tip 0,8 mm, serrated jaw 125 mm, 5" total length	PRO-KL2210
31	"Micro-Halsted" haemostatic forceps curved, tip 0,8 mm, serrated jaw 125 mm, 5" total length	PRO-KL2211
32	"Providence-Hospital" haemostatic forcep straight, tip 1,8 mm, very delicate 140 mm, 5 1/2" total length	PRO-KL2310
33	"Pean" haemostatic forceps, delicate straight, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3030
34	"Dandy" haemostatic forceps curved, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2350
35	"Kocher-Ochsner" haemostatic forceps cur., tip 3,0 mm, 1x2 teeth, serrated jaw 185 mm, 7 1/4" total length	PRO-KL3323
36	"Chusing" micro and suture hook, large ball tip, 2,6 mm neck, round 190 mm, 7 1/2" total length	PRO-WH0370
37	"Frazier" dura hook sharp, tip 0,5 mm 125 mm, 5" total length	PRO-MN3590
38	Wound retractor, delicate model small curve, 1 tooth, sh. 165 mm, 6 1/2" total length	PRO-WH0470
39	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
40	"Baby-Metzenbaum" dissecting scissors bl./bl., cur., tip 1,8 mm 145 mm, 5 3/4" total length	PRO-SC2281
41	"Volkman" retractor 4 teeth, 9x19 mm, sharp 220 mm, 8 3/4" total length	PRO-WH1150
42	"Weitlaner" self-retaining retractor sharp, 3/4 teeth 165 mm, 6 1/2" total length	PRO-WH5200
43	"WEITLANER" WOUNDRETRACTOR, SHARP 3X4 TEETH, 200 MM, 8" TOTAL LENGTH	PRO-WH5380
44	Wound retractor Mollison sharp 4x4prongs 155mm, 6 1/8" total length	PRO-WH5310
45	Elevator "Williger", 7,0 mm wide, 170mm, 6 1/2" long	PRO-KN0391
46	"Hoen" elevator fig. 1, 7,0 mm 160 mm, 6 1/4" total length	PRO-KN0901
47	Dissector"Langenbeck" 8mm width, 200mm, 8" total length	PRO-KN0410
48	"Freer" elevator double en., 3,7/3,7 mm wide, sharp/blunt 185 mm, 7 1/4" total length	PRO-NS2103
49	"Farabeuf" raspatory straight, 12,5 mm wide 140 mm, 5 1/2" total length	PRO-KN0850
50	"Lambotte" raspatory 15,0 mm wide 210 mm, 8 1/4" total length	PRO-KN0960

Lampiran 2 dari 3 Halaman



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No.	Deskripsi	Tipe / Kode
51	"Volkman" bone curette fig.0, mouth 5,2x7,3 mm 170 mm, 6 3/4" total length	PRO-KN1570
52	"Volkman" bone curette fig.1, mouth 6,8x9,5 mm 170 mm, 6 3/4" total length	PRO-KN1580
53	"Olivecrona"micro spatula, with concav and convex endings, width 7 mm a. 9 mm 180 mm, 7 1/8" total length	PRO-MN3190
54	"Olivecrona"micro spatula, with concav and convex endings, width 11 mm a. 13 mm 180 mm, 7 1/8" total length	PRO-MN3200
55	"Olivecrona"micro spatula, with concav and convex endings, width 15 mm a. 18 mm 180 mm, 7 1/8" total length	PRO-MN3210
56	"Olivecrona"micro spatula, with concav and convex endings, width 18 mm a. 22 mm 180 mm, 7 1/8" total length	PRO-MN3220
57	"Davis" dissector curved, double ended, 245 mm, 9 3/4", total length	PRO-MN3550
58	"Penfield" dissector curved, double ended, 6,7/6,5 mm 175 mm, 7" total length	PRO-MN3500
59	"Penfield" dissector curved, double ended, 6,6/3,8 mm 195 mm, 7 3/4" total length	PRO-MN3510
60	"Penfield" dissector fig. 3, double ended 195 mm, 7 3/4" total length	PRO-MN3520
61	"Penfield" dissector curv.,one ended, 3,0 mm wide,round handl 205 mm, 8 1/8" total length	PRO-MN3530
62	"Penfield" dissector curved, double ended, 9,0/6,5 mm 290 mm, 11 1/2" total length	PRO-MN3540
63	"Rhoton" micro hook 90° angled, tip 0,7 mm, blunt 180 mm, 7 1/8" total length	PRO-MN1839
64	"Krayenbuehl" vessel hook small, smooth 185 mm, 7 1/4" total length	PRO-MN1930
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, 08 November 2020



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GA-01

BASIC NEUROSURGERY SET



LP: 04-09-04/0

1 pcs.

REF PRO-SC0870

LOT 20064795

06.09.2018



Power TC surgical scissors, sh./bl., straight, 145 mm 5 3/4" 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 ob Eck, info@asanus.de





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R<sub>X</sub> ONLY

GA-01



BASIC NEUROSURGERY SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-SK0426

**LOT** 21802447

26.06.2018



(01)04060414171334

(10)21802447

**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**

KEMENKES RI AKL.....  
Diproduksi oleh :  
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**AUF: 20192065/20**



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GA-01



**BASIC NEUROSURGERY SET**

**LP: 05-02-11/6**

**1 pcs.**

**REF PRO-PZ0160**

**LOT 21803269**



**29.08.2018**



Anatomic tissue forceps str., tip 2,6 mm, serrated,  
flat handle 180 mm, 7 1/8" 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**

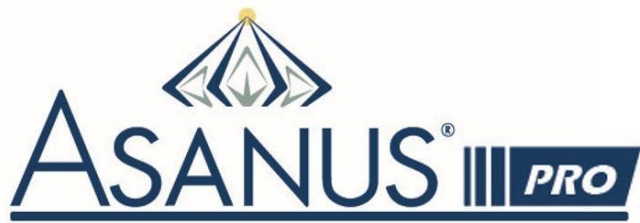
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
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**AUF: 20192065/30**



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GA-01



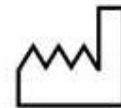
BASIC NEUROSURGERY SET

LP: 03-05-14/4

1 pcs.

REF PRO-SD0400

LOT 21901853



13.05.2019

Double ended probe tip Ø 1,5 mm 145 mm, 5 3/4" total length



(01)04060414210095

(10)21901853

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

Diimport oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/80



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GA01



BASIC NEUROSURGERY SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-SG0181

**LOT** 21901493



23.04.2019



"Frazier" suction tube, angled Charriere 10, Ø 3 mm 130 mm, 5 1/8" 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

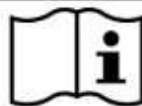
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
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**AUF: 20192065/70**



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GA01



BASIC NEUROSURGERY SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-NH1240

**LOT** 21901493

23.04.2019



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

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

**AUF: 20192065/70**



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GA-01



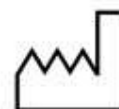
BASIC NEUROSURGERY SET

LP: 02-06-13/7

1 pcs.

**REF** PRO-ND2380

**LOT** 21800225



19.01.2018



"Deschamp" ligature needle for right hand, blunt  
210 mm, 8 1/4" 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.....

Diproduksi oleh :

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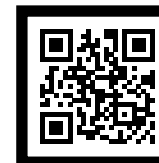
Diimpor oleh :

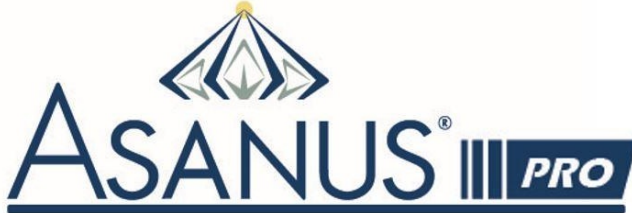
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**AUF: 20192065/160**



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GA-01



BASIC NEUROSURGERY 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

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

**AUF: 20192065/100**



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GA-01



BASIC NEUROSURGERY 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

KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
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AUF: 20192065/130



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GA-01



BASIC NEUROSURGERY 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

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AUF: 20192065/150



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