



**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 11002026652**

Nama Dagang / Merek : **ASANUS PRO Craniotomy 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, 06 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 11002026652**

No.	Deskripsi	Tipe / Kode
1	Scalpel handle No.4, short for blades fig. 18-36 135 mm, 5 1/4" total length	PRO-SK0432
2	"Mayo" dissecting scissors bl./bl., str., tip 3,5 mm 170 mm, 6 3/4" total length	PRO-SC1932
3	Dissecting scissors a. Mayo, curved, 155 mm 6 1/8" total length	PRO-SC1941
4	"Metzenbaum" dissecting scissors bl./bl., straight, 180 mm 7 1/8" total length	PRO-SC2304
5	"Adson" anatomic forceps str., tip 1,5 mm, serrated, flat handle 120 mm, 4 3/4" total length	PRO-PZ0560
6	"Adson" surgical forceps str., tip 1,2 mm, 1x2 teeth, flat handle 120 mm, 4 3/4" total length	PRO-PZ1051
7	"Cushing" anatomic forceps str., tip 1,5 mm, serrated, fl handle 175 mm, 7" total length	PRO-PZ0586
8	"Cushing" surgical forceps str., tip 2,0 mm, 1x2 teeth, flat handle 175 mm, 7" total length	PRO-PZ1672
9	"Taylor" anat.forceps, bayo.shaped hand. str., tip 1,6 mm, with scraper 175 mm, 7" total length	PRO-PZ0344
10	"Taylor" surgical forceps,bayonet-shaped str., tip 1,6mm, 1x2 teeth, w. guide pin 175 mm, 7" total length	PRO-PZ1678
11	"Frazier" suction tube, angled Charriere 10, Ø 3 mm 130 mm, 5 1/8" total length	PRO-SG0181
12	"Frazier" suction tube Charriere 12, 4,0mm diameter 125 mm, 5" working length	PRO-SG0182
13	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230
14	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
15	"Dandy" haemostatic forceps curved, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2350
16	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
17	"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL0470
18	"Cushing" vein retractor with fenestrated handle	PRO-WH0139
19	"WEITLANER" WOUNDRETRACTOR, SHARP 3X4 TEETH, 200 MM, 8" TOTAL LENGTH	PRO-WH5380
20	"Volkman" bone curette fig.000, mouth 3,6x5,5 mm 170 mm, 6 3/4" total length	PRO-KN1550
21	"Volkman" bone curette fig.1, mouth 6,8x9,5 mm 170 mm, 6 3/4" total length	PRO-KN1580
22	"Jansen" bone rongeur straight, mouth bite 22,0 mm 175 mm, 7" total length	PRO-KN4740
23	"Luer" bone rongeur curved 175 mm, 7" total length	PRO-KN4850

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 BSR.E.



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No.	Deskripsi	Tipe / Kode
24	"Luer-Stille" bone rongeur straight, 9,5x15 mm jaw 225 mm, 9" total length	PRO-KN5050
25	"Dahlgren" skull punch with 2 extra hooks 210 mm, 8 1/4" long	PRO-MN2860
26	"Spurling" rongeur straight, mouth 10 x 4 mm 180 mm, 7 1/8" length of shaft	PRO-MN4560
27	"Oldberg" rongeur straight, mouth Ø 7 mm 180 mm, 7 1/8" working length	PRO-MN4113
28	"Schmieden-Taylor" dura scissors angled to side, 1 probe-tip blade 170 mm 6 3/4" total length	PRO-SC2750
29	"Heifetz" brain spatula 20,0 mm wide, malleable, with round handle 200 mm, 8" total length	PRO-MN3290
30	"Olivecrona" micro spatula, with concav and convex endings, width 11 mm a. 13 mm 180 mm, 7 1/8" total length	PRO-MN3200
31	"Frazier" suction cannula curved, Ø 2,0 mm = 6 charrier 195 mm, 7 3/4" total length	PRO-SG0736
32	"Dandy" micro hook str., blunt, mouth part 3,5x5,5 mm 210 mm, 8 1/4" total length	PRO-NS3190
33	Cushing wound retractor fig. 2, blunt, 1 blade 9x10 mm 200 mm, 8" total length	PRO-WH0848
34	"Hudson" handdrill, set, incl. brace, extension piece, 6 drill 270 mm, 10 3/4" total length	PRO-MN2730
35	"Hudson" handdrill, only 270 mm, 10 3/4" total length	PRO-MN2740
36	"Hudson" extension piece for handdrill 97 mm, 4" total length	PRO-MN2750
37	"Hudson" drill, only Ø 9,0 mm, cylindrical 96 mm, 3 3/4" total length	PRO-MN2780
38	"Hudson" drill, only Ø 14,0 mm, cone-shaped 97 mm, 3 3/4" total length	PRO-MN2790
39	"Hudson" drill, only Ø 16,0 mm, ball-shaped 100 mm, 4" total length	PRO-MN2800
40	"Hudson" drill, only Ø 22,0 mm, ball-shaped 102 mm, 4" total length	PRO-MN2810
41	"Mc Kenzie" drill, only Ø 13 mm, spiraled 98 mm, 4" total length	PRO-MN2830
42	"Cushing" craniotomy driller Ø 14,0 mm 94 mm, 3 3/4" total length	PRO-MN2840
43	Wire saw "Gigli" package of 5 pieces, 300 mm, 12" total length	PRO-AP0550
44	Wire saw "Gigli" package of 5 pieces 400 mm total length	PRO-AP0560
45	Wire saw "Gigli" package of 5 pieces 500 mm total length	PRO-AP0570
46	"Gigli" handle for wire saws hooked cur., handle wide 62,3 mm 60 mm, 2 1/4" total length	PRO-AP0590
47	Conductor for Gigli and Olivecrona wire saws, soft, flexible 310 mm, 12 1/4" total length	PRO-MN2870
48	"Raney" scalp hemostasis clip skin clip, chromed 1 Pck. / 25 pcs.	PRO-MN2600
49	"Raney" applying/removal forceps for scalp clips 160 mm, 6 1/4" total length	PRO-MN2620
50	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
51	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
52	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

Lampiran 2 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.

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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
tercantum dalam lampiran ini		

Jakarta, 06 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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GA-01



CRANIOTOMY 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 :

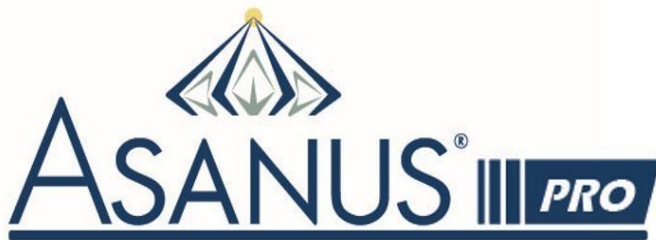
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/40



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GA-01



CRANIOTOMY SET

LP: 14-03-05/2

1 pcs.

REF PRO-SK0432

LOT 21802447



Scalpel handle No.4, short for blades fig. 18-36 135 mm,  
5 1/4" total length

26.06.2018

(01)04060414171334

(10)21802447

Date: 14.10.2019

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

Your order no.: sample labels, 14.10.2019

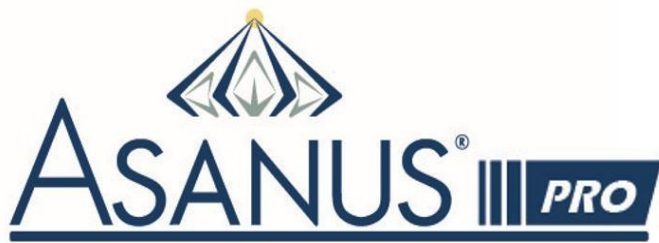
KEMENKES RI AKL.....  
Diproduksi oleh :  
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Diimpor oleh :  
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AUF: 20192065/20



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GA-01



CRANIOTOMY SET

LP: 05-02-11/6

1 pcs.

**REF** PRO-PZ1672

**LOT** 21803269



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

29.08.2018

(01)04060414159349

(10)21803269

**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 :  
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Diimpor oleh :  
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**AUF: 20192065/30**



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GA-01



CRANIOTOMY SET

LP: 03-05-14/4

1 pcs.

REF PRO-KN4850

LOT 21901853



13.05.2019



"Luer" bone rongeur curved 175 mm, 7" 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

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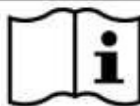
AUF: 20192065/80



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GA01



CRANIOTOMY SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-MN2860

**LOT** 21901493

23.04.2019



"Dahlgren" skull punch with 2 extra hooks 210 mm, 8 1/4" long

(01)04060414179705

(10)21901493

**Date: 15.10.2019**

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

**Your order no.: sample labels, 14.10.2019**

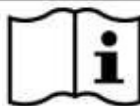
KEMENKES RI AKL.....  
Diproduksi oleh :  
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Diimpor oleh :  
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GA01



CRANIOTOMY SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-WH0848

**LOT** 21901493



Cushing wound retractor fig. 2, blunt, 1 blade 9x10 mm  
200 mm, 8" total length

23.04.2019

(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 :  
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GA-01



CRANIOTOMY SET

LP: 02-06-13/7

1 pcs.

REF PRO-AP0550

LOT 21800225

19.01.2018



Wire saw "Gigli" package of 5 pieces, 300 mm, 12" 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



CRANIOTOMY 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

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....  
Diproduksi oleh :  
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GA-01



CRANIOTOMY 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 :  
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Diimpor oleh :  
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GA-01



CRANIOTOMY 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 :

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