



**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 11303026651**

Nama Dagang / Merek : **ASANUS PRO Major Orthopaedic Set**  
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A  
Kategori Produk : Peralatan Ortopedi  
Sub Kategori : Peralatan Ortopedi Bedah  
Jenis Produk : Orthopedic manual surgical 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 11303026651**

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.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 210 mm, 8 1/4" total length	PRO-SK0427
4	Power TC surgical scissors, sh./bl., straight, 145 mm 5 3/4" total length	PRO-SC0870
5	Surgical scissors bl./bl., cur., tip 7,2 mm 145 mm 5 3/4" total length	PRO-SC1463
6	"Ultra-Cut" Mayo-Stillie diss. scissors curved, 170 mm 6 3/4" total length,	PRO-SC5815
7	"Metzenbaum-Fino" power TC diss.scissors bl./bl., curved, very delicate shanks 230 mm 9 1/8" total length	PRO-SC0989
8	Anatomic forceps, standard straight, tip 3,5 mm, serrated 150 mm, 6" total length	PRO-PZ0245
9	Anatomic tissue forceps str., tip 2,6 mm, serrated, flat handle 180 mm, 7 1/8" total length	PRO-PZ0160
10	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
11	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 200 mm, 8" total length	PRO-PZ1290
12	Surgical forceps str., tip 1,7 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1150
13	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
14	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
15	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
16	"Pean" haemostatic forceps, delicate straight, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3030
17	"Pean" haemostatic forceps, delicate curved, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3031
18	"Rochester-Pean" haemostatic forceps straight, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3084
19	"Rochester-Pean" haemostatic forceps curved, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3085
20	"Kocher-Ochsner" haemostatic forceps str., tip 3,4mm,1x2 teeth, serrated jaw 200 mm, 8" total length	PRO-KL3324
21	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
22	"Ulrich" sponge-/dressing-/wash forceps straight 220 mm, 8 3/4" total length	PRO-KL0300

Lampiran 1 dari 3 Halaman



Catatan:

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- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



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No.	Deskripsi	Tipe / Kode
23	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
24	"Volkman" retractor 4 teeth, 9x19 mm, sharp 220 mm, 8 3/4" total length	PRO-WH1150
25	"Volkman" retractor sharp, blade 20x0,7 mm 220 mm, 8 3/4" total length	PRO-WH1110
26	"Volkman" retractor blunt, blade 20x2,8 mm 220 mm, 8 3/4" total length	PRO-WH1120
27	Langenbeck retractor 83x15mm, 215mm, 8 1/2" total length	PRO-WH1590
28	Dissector"Langenbeck" 8mm width, 200mm, 8" total length	PRO-KN0410
29	"Sedillot" raspatory 18,0 mm wide 185 mm, 7 1/4" total length	PRO-KN0900
30	Mallet Ø 28 mm and Ø 42 mm, 400 g 240 mm, 9 1/2" total length	PRO-KN2120
31	"Stille" flat chisel 6 mm wide 200 mm, 8" total length	PRO-KN3126
32	"Stille" osteotome straight, mouth 10 mm 205 mm, 8 1/8" total length	PRO-KN3190
33	"Stille" osteotome straight, mouth 15 mm 205 mm, 8 1/8" total length	PRO-KN3210
34	"Stille" osteotome straight, mouth 20 mm 205 mm, 8 1/8" total length	PRO-KN3220
35	"Hibbs" gouge straight, mouth 13 mm 240 mm, 9 1/2" total length	PRO-KN3062
36	"Hibbs" gouge straight, mouth 19 mm 240 mm, 9 1/2" total length	PRO-KN3063
37	"Hibbs" gouge curved, mouth 13 mm 240 mm, 9 1/2" total length	PRO-KN3072
38	"Hibbs" gouge curved, mouth 19 mm 240 mm, 9 1/2" total length	PRO-KN3073
39	"Volkman" bone curette fig.00, mouth 4,4x6,5 mm 170 mm, 6 3/4" total length	PRO-KN1560
40	"Volkman" bone curette fig.0, mouth 5,2x7,3 mm 170 mm, 6 3/4" total length	PRO-KN1570
41	"Volkman" bone curette fig.1, mouth 6,8x9,5 mm 170 mm, 6 3/4" total length	PRO-KN1580
42	"Volkman" bone curette fig.2, mouth 8,5x12,0 mm 170 mm, 6 3/4" total length	PRO-KN1590
43	"Kleinert-Kutz" bone rongeur smooth curved, mouth bite 13,0 mm 150 mm, 6" total length	PRO-KN4931
44	Titanit bone rongeur Ruskin 6x15 mm bite straight 180 mm, 7 1/8" long	PRO-KN4962T
45	"Ruskin-Liston" bone cutter straight, length of cut 25,0 mm 190 mm, 7 1/2" total length	PRO-KN5300
46	"Verbrugge" bone holding forceps curved, extra small, mouth width 5 mm 175 mm, 7" total length	PRO-KN4510
47	"Verbrugge" bone holding forceps, curv. fig.1, mouth width left 4 mm/right 10 mm 250 mm, 10 1/8" total length	PRO-KN4520
48	"Verbrugge" bone holding forceps, curv. fig.3, mouth width left 4,5mm/right 12mm 270 mm, 10 3/4" total length	PRO-KN4540
49	Reposition forceps with thread fixation, large 220 mm, 8 3/4" total length	PRO-KN4200
50	Reposition forceps with thread fixation, small 170 mm, 6 3/4" total length	PRO-KN4190

Lampiran 2 dari 3 Halaman



Catatan:

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No.	Deskripsi	Tipe / Kode
51	Reposition forceps 40° angled, for small fragments 135 mm, 5 1/4" total length	PRO-KN4100
52	Adson woundretractor blunt 4X5 teeth right 5 teeth, left 4 teeth 320 mm, 12 3/4" total length	PRO-WH5371R
53	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
54	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
55	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, 06 November 2020



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GA-01



MAJOR ORTHOPAEDIC 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





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GA-01



MAJOR ORTHOPAEDIC 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 :  
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Rx ONLY

GA-01



MAJOR ORTHOPAEDIC SET

LP: 05-02-11/6

1 pcs.

REF PRO-PZ1260

LOT 21803269

29.08.2018



Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length

(01)04060414159349

(10)21803269

Date: 14.10.2019

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

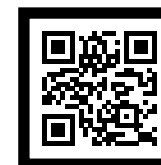
Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....  
Diproduksi oleh :  
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AUF: 20192065/30



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GA-01



MAJOR ORTHOPAEDIC SET

LP: 03-05-14/4

1 pcs.

**REF** PRO-SC0870

**LOT** 21901853



13.05.2019

Power TC surgical scissors, sh./bl., straight, 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 :

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Diimpor oleh :

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**AUF: 20192065/80**



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GA01



MAJOR ORTHOPAEDIC SET

LP: 05-11-03/8

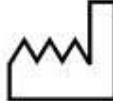
1 pcs.

**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

Your order no.: sample labels, 14.10.2019

KEMENKES RI AKL.....  
Diproduksi oleh :  
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Diimpor oleh :  
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**AUF: 20192065/70**



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GA01



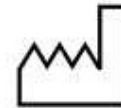
MAJOR ORTHOPAEDIC SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-WH1110

**LOT** 21901493



23.04.2019



"Volkmann" retractor sharp, blade 20x0,7 mm 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**

KEMENKES RI AKL.....

Diproduksi oleh :

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**AUF: 20192065/70**



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GA-01



MAJOR ORTHOPAEDIC SET

LP: 02-06-13/7

1 pcs.

**REF** PRO-KN2120

**LOT** 21800225

19.01.2018



Mallet Ø 28 mm and Ø 42 mm, 400 g 240 mm, 9 1/2" 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**

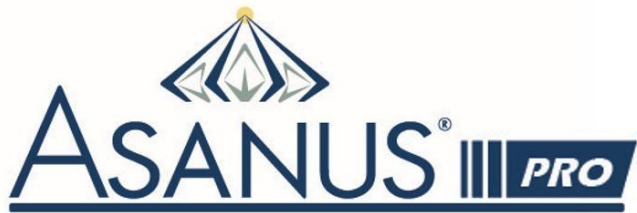
KEMENKES RI AKL.....  
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**AUF: 20192065/160**



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GA-01



MAJOR ORTHOPAEDIC 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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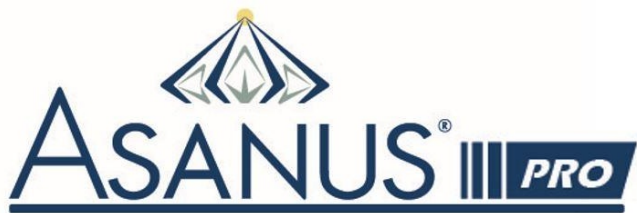
**AUF: 20192065/100**



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GA-01



MAJOR ORTHOPAEDIC SET

LP: 08-03-05/5

1 pcs.

REF PRO-ST5783

LOT 20190853

24.04.2019



(01)04060414203707

(10)21901531

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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AUF: 20192065/130



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GA-01



MAJOR ORTHOPAEDIC 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 :  
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Diimpor oleh :  
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**AUF: 20192065/150**



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