



**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 11603025517

Nama Dagang / Merek : **ASANUS PRO Major Basic 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, 22 September 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 11603025517

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	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
4	Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0204
5	Anatomic forceps, standard straight, tip 3,8 mm, serrated 180 mm, 7 1/8" total length	PRO-PZ0260
6	Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 8" total length	PRO-PZ0270
7	"Cushing" anatomic forceps str., tip 1,2 mm, serrated, fl handle 180 mm, 7 1/8" total length	PRO-PZ0640
8	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
9	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 180 mm, 7 1/8" total length	PRO-PZ1280
10	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 200 mm, 8" total length	PRO-PZ1290
11	"Waugh" surgical forceps str, tip 2,0mm,1x2 teeth, cross serrated 180 mm, 7 1/8" total length	PRO-PZ1560
12	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230
13	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
14	"Rochester-Pean" haemostatic forceps straight, tip 3,0 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3080
15	"Rochester-Pean" haemostatic forceps curved, tip 3,0 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3081
16	"Kocher-Ochsner" haemostatic forceps str., tip 2,7mm,1x2 teeth, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3320
17	"Mikulicz" peritoneum forceps curv.,tip 3,0 mm,1x2 teeth, serrated jaw 185 mm, 7 1/4" total length	PRO-KL4560
18	"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" total length	PRO-SC1930
19	"Mayo" dissecting scissor curved, 140 mm 5 1/2" total length	PRO-SC1940
20	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
21	"Volkman" retractor 6 teeth, 8x29 mm, blunt 220 mm, 8 3/4" total length	PRO-WH1210
22	"Roux" retractor, double ended 1 set/3 pieces (PRO-WH0250/PRO-WH0260/PRO-WH0270) 165 mm, 6 1/2" total length	PRO-WH0240

Lampiran 1 dari 2 Halaman



Catatan:

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



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DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN

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Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
23	"Roux" retractor, double ended 19x22 / 23x30 mm 145 mm, 5 3/4" total length	PRO-WH0250
24	Roux woundretractor double ended 155mm, 6 1/8" total length	PRO-WH0260
25	Roux hook woundretractor double , big 165mm, 6 1/2" total length	PRO-WH0270
26	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
27	"Kocher" retractor blunt, blade 60x12 mm 210 mm, 8 1/4" total length	PRO-WH1739
28	"Fritsch" abdominal retractor fig. 1, blunt, blade 32x40 mm 250 mm, 10" total length	PRO-WH2730
29	"Kocher" retractor 60x25 mm 230 mm, 9 1/8" total length	PRO-WH1760
30	Abdominal/intestinal spatula blade 25 mm wide, malleable 250 mm, 10" total length	PRO-WH3095
31	"Cushing" vein retractor with fenestrated handle	PRO-WH0139
32	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
33	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
34	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
35	"Overholt-Geissendörfer" dissecting for. curved, tip 2,4 mm, serrated jaw 220 mm, 8 3/4" total length	PRO-KL4160
36	"Overholt-Geissendörfer" dissecting forc curved, tip 1,8 mm, serrated jaw 195 mm, 7 3/4" total length	PRO-KL4120
37	"Overholt-Geissendörfer" dissecting for. strong curv., tip 2,5 mm, serrated jaw 230 mm, 9 1/8" total length	PRO-KL4170
38	"Duval" lung grasping forceps 21 mm wide 230 mm, 9 1/8" total length	PRO-GF3639
39	"Nelaton" probe curved, bluntt 160 mm, 6 1/4" total length	PRO-SD0140
40	Double ended probe tip Ø 2,0 mm 200 mm, 8" total length	PRO-SD0480
41	Needle case, perforated with 7 compartments 150 x 95 x 13 mm	PRO-ND0880
42	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
43	Bowl stainless steel capacity 0,1 L, Ø 80 mm 35 mm height	PRO-SL0990
44	Bowl stainless steel capacity 0,3 L, Ø 100 mm 65 mm height	PRO-SL0992
45	Kidney tray stainless steel capacity 0,50 L, height 39 mm 250 mm, 10" total length	PRO-SL0125
46	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
47	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
48	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, 22 September 2020

Ditandatangani Secara Elektronik Oleh :
 a.n Direktur Jenderal
 Direktur Penilaian Alat Kesehatan dan PKRT
KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
 Dr. IGM. Wirabrata, Apt
 NIP. 19751206 200312 1 001

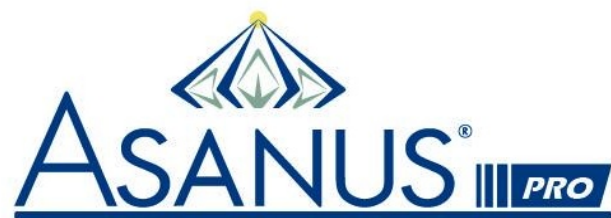


Catatan:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

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GA-01



MAJOR BASIC 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 :

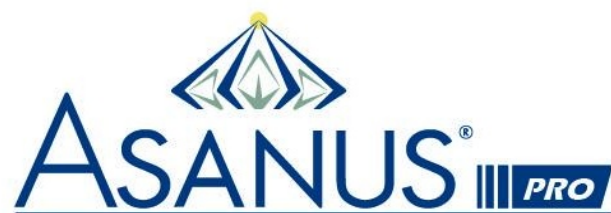
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/40



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





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GA-01



MAJOR BASIC 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

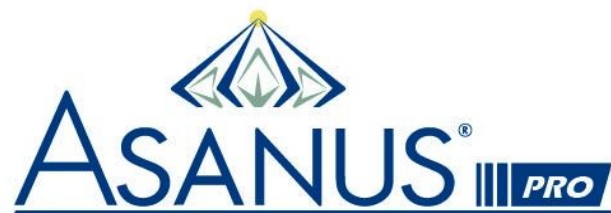
KEMENKES RI AKL.....
Diproduksi oleh :
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Diimpor oleh :
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AUF: 20192065/20



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Rx ONLY

GA-01



MAJOR BASIC SET

LP: 05-02-11/6

1 pcs.

REF PRO-PZ0260

LOT 21803269



29.08.2018



(01)04060414159349

(10)21803269

Date: 14.10.2019

Anatomic forceps, standard straight, tip 3,8 mm, serrated 180 mm, 7 1/8" total length

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

Your order no.: sample labels, 14.10.2019

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Diimpor oleh :
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/30



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Rx ONLY

GA-01



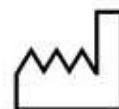
MAJOR BASIC SET

LP: 03-05-14/4

1 pcs.

REF PRO-SC1930

LOT 21901853



13.05.2019



"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" 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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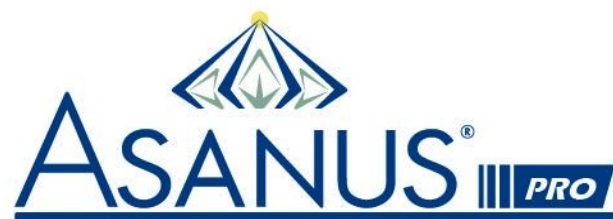
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AUF: 20192065/80



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GA01



MAJOR BASIC SET

LP: 05-11-03/8

1 pcs.

REF PRO-WH1210

LOT 21901493



23.04.2019



(01)04060414179705

(10)21901493

Date: 15.10.2019

"Volkmann" retractor 6 teeth, 8x29 mm,
blunt 220 mm, 8 3/4" 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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Diimpor oleh :

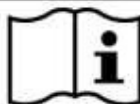
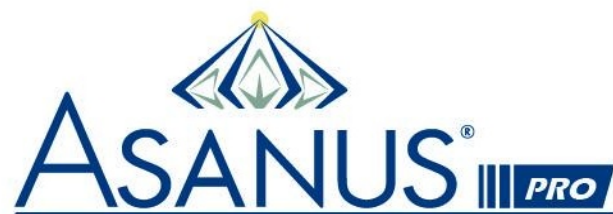
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/70



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GA01



MAJOR BASIC SET

LP: 05-11-03/8

1 pcs.

REF PRO-SD0480

LOT 21901493



23.04.2019



Double ended probe tip Ø 2,0 mm 200 mm,
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.....

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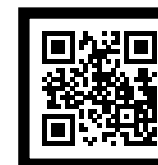
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AUF: 20192065/70



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GA-01



MAJOR BASIC SET

LP: 02-06-13/7

1 pcs.

REF PRO-SG0840

LOT 21800225

19.01.2018



(01)04060414181975

(10)21800225

Date: 15.10.2019

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

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

Your order no.: sample labels, 14.10.2019

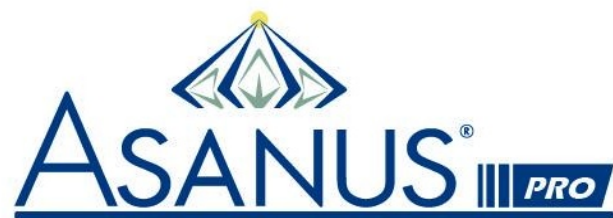
KEMENKES RI AKL.....
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AUF: 20192065/160



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GA-01



MAJOR BASIC 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

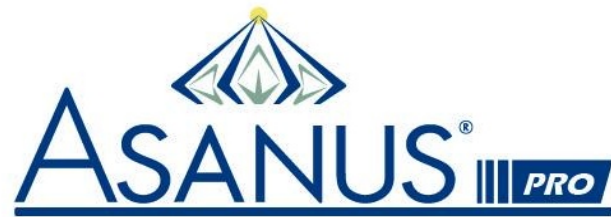
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AUF: 20192065/100



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GA-01



MAJOR BASIC 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

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AUF: 20192065/130



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GA-01



MAJOR BASIC 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.....
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