



**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 11603025311

Nama Dagang / Merek : **ASANUS PRO Basic Plastic Surgery 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, 14 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 11603025311**

No.	Deskripsi	Tipe / Kode
1	"Maier" sponge-/dressing forceps without lock, curved 265 mm, 10 1/2" total length	PRO-KL0270
2	"Backhaus" towel clamp curved, tip 1,5 mm, sharp 110 mm, 4 1/4" total length	PRO-KL0750
3	Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
4	"Crile" haemostatic forceps straight, tip 1,6 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2390
5	"Baby-Crile" haemostatic forceps curved, tip 2,0 mm, 1x2 teeth 140 mm, 5 1/2" total length	PRO-KL2431
6	"Baby-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 100 mm, 4" total length	PRO-KL2191
7	sponge forceps curved, with ratchet 175 mm, 7" total length	PRO-KL0160
8	Surgical forceps str., tip 1,7 mm, 1x2 teeth, flat handle 130 mm, 5 1/8" total length	PRO-PZ1140
9	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 130 mm, 5 1/8" total length	PRO-PZ1250
10	"Adson" TC-vessel forceps straight, tip 1,5 mm, with TC-tip 120 mm, 4 3/4" total length	PRO-PZ0380
11	"Adson" surgical TC-forceps str, tip 1,5mm, 1x2 teeth, witho. TC-tip 120 mm, 4 3/4" total length	PRO-PZ0385
12	"Micro-Adson" surgical forceps str., tip 1,0 mm, 1x2 teeth, flat handle 150 mm, 6" total length	PRO-PZ1100
13	Power TC surgical scissors, sh./bl., straight, 145 mm 5 3/4" total length	PRO-SC0870
14	Surgical scissors sh./bl., cur., tip 5,0 mm 145 mm, 5 3/4" total length	PRO-SC1517
15	"Mayo-Lexer" dissecting scissors bl./bl., cur., tip 2,8 mm 165 mm, 6 1/2" total length	PRO-SC2260
16	"Ultra-Cut" Metzenbaum diss. scissors bl./bl., curved 145 mm 5 3/4" total length	PRO-SC5001
17	"Kilner" dissecting scissors a. Kilner curved, with flat point 150 mm 6" total length	PRO-SC0651
18	"Metzenbaum" dissecting scissor bl./bl., str., tip 2,8 mm 145 mm, 5 3/4" total length	PRO-SC2300
19	Dissecting and strabismus scissors bl./bl., curved, 115 mm 4 1/2" total length	PRO-SC0640
20	Umbilical cord scissors, curved, 130 mm, 5 1/8" total length	PRO-SC3070
21	"Lister" bandage- and cloth scissors ang., 1 blade with ball tip, 120 mm 4 3/4" total length	PRO-SC3222
22	"Langenbeck" retractor blunt, blade 40x11 mm 210 mm, 8 1/4" total length	PRO-WH1520
23	"Langenbeck" retractor 30x16 mm 210 mm, 8 1/4" total length	PRO-WH1495

Lampiran 1 dari 2 Halaman



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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
24	"Volkman" retractor 4 teeth, 8x19 mm, blunt 220 mm, 8 3/4" total length	PRO-WH1200
25	"Senn-Miller" retractor, double ended 8x7 mm (3-teeth bl.) & 18x5,5 mm hooks 160 mm, 6 1/4" total length	PRO-WH0131
26	"Desmarres" lid retractor 11x14 mm 140 mm, 5 1/2" total length	PRO-AU0380
27	"Desmarres" lid retractor 12x16 mm 140 mm, 5 1/2" total length	PRO-AU0390
28	"Gilles" skin retractor large, Ø 3,5mm, str., sharp 180 mm, 7 1/8" total length	PRO-NS3010
29	Wound retractor, delicate model small curve, 1 tooth, sh. 165 mm, 6 1/2" total length	PRO-WH0470
30	Retractor, small curve, 1 prong blunt, 165 mm, 6 1/2" total length	PRO-WH0510
31	"Volkman" bone curette fig.4, mouth 11,5x15,5 mm 170 mm, 6 3/4" total length	PRO-KN1610
32	"Volkman" bone curette fig.5, mouth 13,0x17,8 mm 170 mm, 6 3/4" total length	PRO-KN1620
33	"Czerny" uterine tenaculum forceps 4x4 teeth, straight, 11 mm wide 200 mm, 8" total length	PRO-GY2650
34	"Mathieu" abdominal/intestinal spatula blade 25 mm wide, malleable 200 mm, 8" total length	PRO-WH3090
35	Strabismus hook "Graefe" short 140 mm 5 1/2" total length	PRO-AU0500
36	Double ended probe tip Ø 1,0 mm 145 mm, 5 3/4" total length	PRO-SD0380
37	Double ended probe tip Ø 1,5 mm 160 mm, 6 1/4" total length	PRO-SD0410
38	Double ended probe tip Ø 2,0 mm 180 mm, 7 1/8" total length	PRO-SD0470
39	"Crile-Murray" needle holder straight, tip 1,9 mm, needle size 4-6 mm 150 mm, 6" total length	PRO-NH1190
40	"Halsey" power TC needle holder straight, tip 1,5 mm, needle size 5-7 mm 130 mm, 5 1/8" total length	PRO-NH0190
41	Needle holder a. Crile - Wood delicate 150 mm 6" total length	PRO-NH1180
42	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
43	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
44	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, 14 September 2020

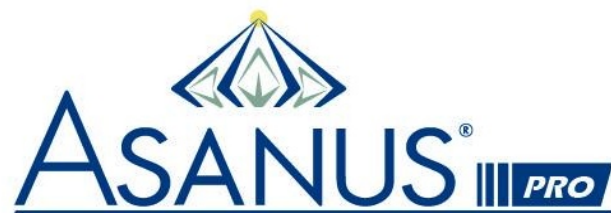


Catatan:

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GA-01



BASIC PLASTIC SURGERY SET

LP: 10-03-03/2

1 pcs.

REF PRO-SK0426

LOT 21602426

10.05.2016



(01)04060414000269

(10)21602426

Date: 15.10.2019

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

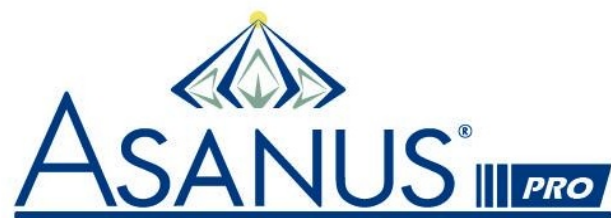
KEMENKES RI AKL.....
Diproduksi oleh :
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany
Diimpor oleh :
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/240



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





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GA-01



BASIC PLASTIC SURGERY 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

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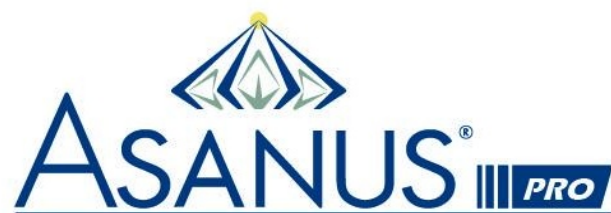
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AUF: 20192065/40



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GA-01



BASIC PLASTIC SURGERY SET

LP: 14-03-05/2

1 pcs.

REF PRO-SC0651

LOT 21802447



26.06.2018



"Kilner" dissecting scissors a. Kilner curved, with flat point 150 mm 6" 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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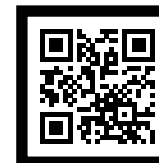
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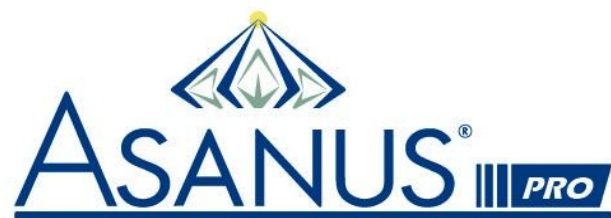
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AUF: 20192065/20



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GA-01



BASIC PLASTIC SURGERY SET

LP: 02-03-11/2

1 pcs.

REF PRO-NH1190

LOT 21605437

28.09.2016



"Crile-Murray" needle holder straight, tip 1,9 mm, needle size 4-6 mm 150 mm, 6" total length

(01)04060414139372

(10)21605437

Date: 14.10.2019

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

Your order no.: sample labels, 14.10.2019

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Rx ONLY

GA-01



BASIC PLASTIC SURGERY SET

LP: 05-02-11/6

1 pcs.

REF PRO-PZ1140

LOT 21803269



29.08.2018



Surgical forceps str., tip 1,7 mm, 1x2 teeth, flat handle 130 mm, 5 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

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AUF: 20192065/30



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BASIC PLASTIC SURGERY SET

LP: 03-05-14/4

GA-01

1 pcs.



REF PRO-WH1520

"Langenbeck" retractor blunt, blade 40x11 mm 210 mm, 8 1/4" total length

LOT 21901853

 13.05.2019



(01)04060414210095

(10)21901853

Date: 15.10.2019

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

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AUF: 20192065/80



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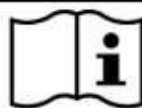
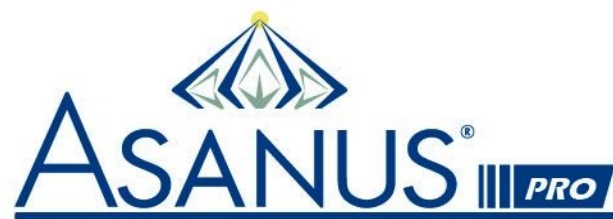


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GA01



BASIC PLASTIC SURGERY SET

LP: 05-11-03/8

1 pcs.

REF PRO-SD0380

LOT 21901493



23.04.2019



(01)04060414179705

(10)21901493

Date: 15.10.2019

Double ended probe tip Ø 1,0 mm 145 mm,
5 3/4" 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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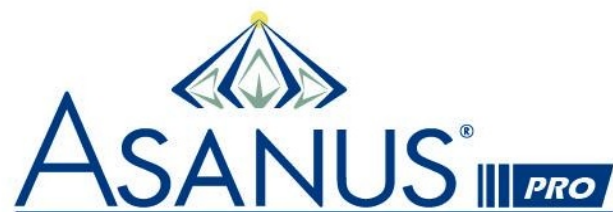
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GA-01



BASIC PLASTIC SURGERY 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

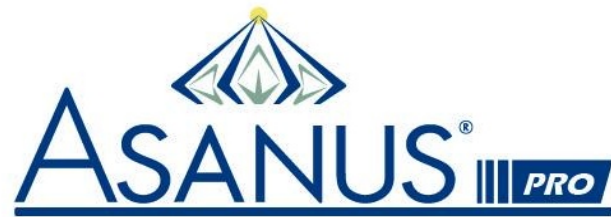
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AUF: 20192065/100



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GA-01



BASIC PLASTIC SURGERY 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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GA-01



BASIC PLASTIC SURGERY 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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