



**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 11303026144

Nama Dagang / Merek : **ASANUS PRO Orthopaedic Emergency 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, 14 Oktober 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 11303026144**

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	Power TC surgical scissors, sh./sh., straight, 145 mm 5 3/4" total length	PRO-SC0840
4	"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" total length	PRO-SC1930
5	"Mayo" dissecting scissors bl./bl., str., tip 3,5 mm 170 mm, 6 3/4" total length	PRO-SC1932
6	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
7	Surgical forceps str., tip 1,7 mm, 1x2 teeth, flat handle 130 mm, 5 1/8" total length	PRO-PZ1140
8	"Adson" anatomic forceps str., tip 1,5 mm, serrated, flat handle 120 mm, 4 3/4" total length	PRO-PZ0560
9	Anatomic tissue forceps str., tip 1,9 mm, serrated, flat handle 130 mm, 5 1/8" total length	PRO-PZ0130
10	"Foerster" sponge-/dressing forceps straight, smooth jaw 245 mm, 9 3/4" total length	PRO-KL0450
11	"Backhaus" towel clamp curved, tip 1,5 mm, sharp 110 mm, 4 1/4" total length	PRO-KL0750
12	"Baby-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 100 mm, 4" total length	PRO-KL2191
13	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
14	"Kelly" haemostatic forceps curved, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2331
15	"Kocher" haemostatic forceps straight, tip 2,0 mm, 1x2 teeth, delicate 140 mm, 5 1/2" total length	PRO-KL3260
16	"Rochester-Pean" haemostatic forceps straight, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3084
17	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
18	Double ended probe tip Ø 1,5 mm 160 mm, 6 1/4" total length	PRO-SD0410
19	"Nelaton" probe curved, bluntt 160 mm, 6 1/4" total length	PRO-SD0140
20	"Senn-Miller" retractor, double ended 8x7 mm (3-teeth sh.) & 18x5,5 mm hooks 160 mm, 6 1/4" total length	PRO-WH0130
21	Retractor, small curve,4 prongs sharp, 165 mm, 6 1/2" total length	PRO-WH0500
22	"Allis" intestinal grasping forceps straight, tip 5,3 mm, 5x6 teeth 155 mm, 6 1/8" total length	PRO-MD0130
23	"Babcock"atr intestinal grasping forceps straight, tip 8,0 mm, DeBakey teeth 160 mm, 6 1/4" total length	PRO-MD0290

Lampiran 1 dari 2 Halaman



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No.	Deskripsi	Tipe / Kode
24	"Volkman" double bone curette straight, mouth 6,0 / 7,5 mm 130 mm, 5 1/8" total length	PRO-KN1930
25	"Weitlaner" self-retaining retractor with joint, blunt, 4/4 teeth 145 mm 5 3/4" total length	PRO-WH5274
26	"Adson" surgical forceps str., tip 1,1 mm, 1x2 teeth, serrated 120 mm, 4 3/4" total length	PRO-PZ1062
27	"Micro-Adson" surgical forceps str., tip 1,0 mm, 1x2 teeth, flat handle 150 mm, 6" total length	PRO-PZ1100
28	"Micro-Adson" anatomic forceps, delicate str., tip 0,5 mm, serrated, flat handle 150 mm, 6" total length	PRO-PZ0570
29	Retractor, small curve,3 prongs blunt, 165 mm, 6 1/2" total length	PRO-WH0530
30	RETRACTOR, SMALL CURVE,2 PRONGS SHARP, 165 MM, 6 1/2" TOTAL LENGTH	PRO-WH0480
31	"Weitlaner" self-retaining retractor sharp, 2/3 teeth 110 mm, 4 1/4" total length	PRO-WH5180
32	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
33	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
34	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 Oktober 2020

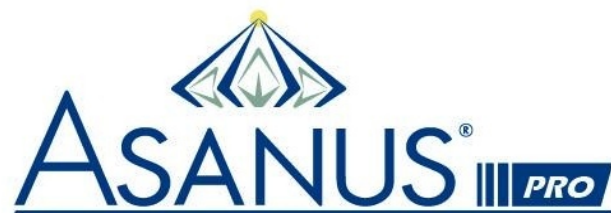


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www.asanus.de



GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-SK0432

LOT 21602426

10.05.2016



(01)04060414000269
(10)21602426

Date: 15.10.2019

Scalpel handle No.4, short for blades fig.
18-36 135 mm, 5 1/4" 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 ob Eck, info@asanus.de





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GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-SC0840

LOT 21502318

10.05.2016



Power TC surgical scissors, sh./sh., straight, 145 mm 5 3/4" total length

(01)04060414000269

(10)21602426

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

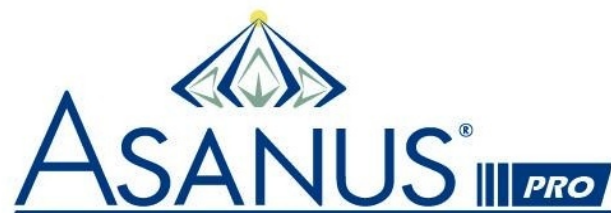
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GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-PZ1140

LOT 21783509

10.05.2016



Surgical forceps str., tip 1,7 mm, 1x2 teeth, flat handle 130 mm, 5 1/8" total length

(01)04060414000269
(10)21602426

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

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GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-KL0450

LOT 21672001

10.05.2016



"Foerster" sponge-/dressing forceps straight, smooth
jaw 245 mm, 9 3/4" total length

(01)04060414000269
(10)21602426

Date: 15.10.2019

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

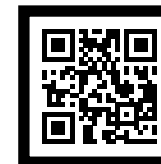
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GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-KL2231

LOT 21689920

10.05.2016



(01)04060414000269

(10)21602426

Date: 15.10.2019

"Halsted-Mosquito" haemostatic forceps curved, tip
1,0 mm, serrated jaw 125 mm, 5" total length

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

Your order no.: sample labels, 14.10.2019

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ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-NH1240

LOT 21689031

10.05.2016



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

(01)04060414000269
(10)21602426

Date: 15.10.2019

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

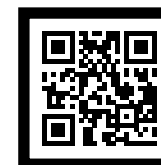
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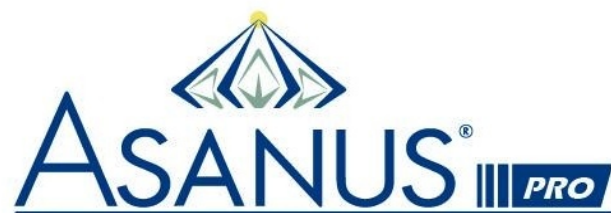
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ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-SD0410

LOT 20927845

10.05.2016



Double ended probe tip Ø 1,5 mm 160 mm, 6 1/4"
total length

(01)04060414000269
(10)21602426

Date: 15.10.2019

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

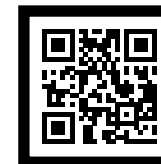
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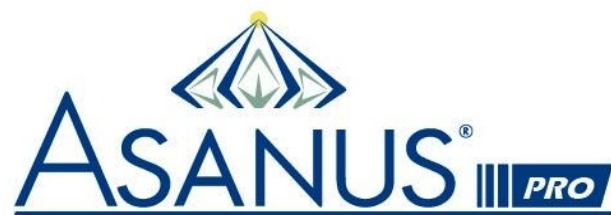
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GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-WH0130

LOT 20166547

10.05.2016



(01)04060414000269
(10)21602426

Date: 15.10.2019

"Senn-Miller" retractor, double ended 8x7 mm
(3-teeth sh.) & 18x5,5 mm hooks 160 mm, 6 1/4"
total length

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

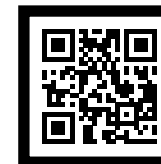
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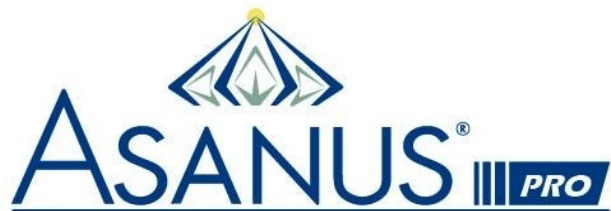
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GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 10-03-03/2 1 pcs.

REF PRO-KN1930

LOT 20160610



10.05.2016

"Volkmann" double bone curette straight, mouth 6,0 /
7,5 mm 130 mm, 5 1/8" total length



(01)04060414000269
(10)21602426

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

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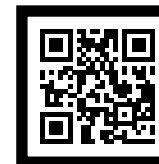
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GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 14-03-05/2 1 pcs.

REF PRO-CE5703S

LOT 20182746

26.06.2018



Cont. 1/1 basic plus model grey bottom
non-perforated 600x285x135mm

(01)04060414171334

(10)21802447

Date: 14.10.2019

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

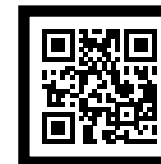
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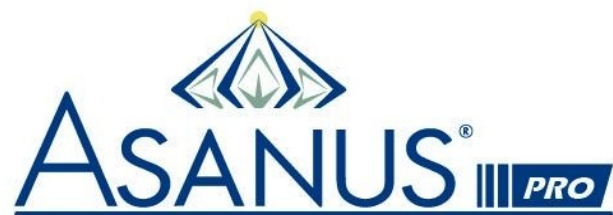
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GA-01



R_X ONLY



ORTHOPAEDIC EMERGENCY SET
LP: 14-03-05/2 1 pcs.

REF PRO-ST5783

LOT 21802447

26.06.2018



Wire basket 1/1, full size, with fall handle
480x250x100 mm

(01)04060414171334

(10)21802447

Date: 14.10.2019

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

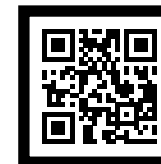
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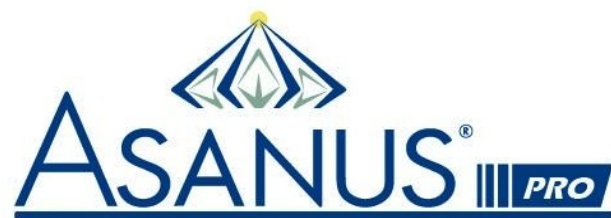
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AUF: 20192065/20



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Rx ONLY

GA-01



ORTHOPAEDIC EMERGENCY SET
LP: 14-03-05/2 1 pcs.

REF PRO-ZB9094

Teflon long time filter for maximum
200 cycles ø 194 mm

LOT 20189421

26.06.2018



(01)04060414171334

(10)21802447

Date: 14.10.2019

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

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