



**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 10703026642

Nama Dagang / Merek : **ASANUS PRO Basic ENT Instrument Set**
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A
Kategori Produk : Peralatan Telinga, Hidung dan Tenggorokan
Sub Kategori : Peralatan Telinga, Hidung dan Tenggorokan Bedah
Jenis Produk : Ear, nose, and throat 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 10703026642**

| No. | Deskripsi | Tipe / Kode |
|-----|--|-------------|
| 1 | Anatomic forceps, delicate str., tip 1,5 mm, serrated, flat handle 155 mm, 6 1/8" total length | PRO-PZ0540 |
| 2 | "Allis" intestinal grasping forceps straight, tip 5,7 mm, 5x6 teeth 190 mm, 7 1/2" total length | PRO-MD0140 |
| 3 | "Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length | PRO-KL2231 |
| 4 | Mouth gag "Whitehead-Jennings" 130 mm 5 1/8" total length | PRO-HA0720 |
| 5 | "Brünings" tongue spatula width of endings 19,5/15,2 mm, light cur 190 mm, 7 1/2" total length | PRO-HA1280 |
| 6 | "Blakesley" nasal forceps str., figure 3, mouth 11x4,8 mm 110 mm, 4 1/4" length of shaft | PRO-NS1240 |
| 7 | "Cottle" chisel 4,0 mm wide, with crossbar 185 mm, 7 1/4" total length | PRO-NS2514 |
| 8 | "Cottle" chisel 6,0 mm wide, with crossbar 185 mm, 7 1/4" total length | PRO-NS2516 |
| 9 | "Cottle septum chisel curved, 6,0 mm wide, graduated 180 mm, 7 1/8" total length | PRO-NS2500 |
| 10 | "Backhaus" towel clamp 90 mm, 3 1/2" total length | PRO-KL0740 |
| 11 | Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length | PRO-SK0426 |
| 12 | "Freer" septum knife 165 mm, 6 1/2" total length | PRO-NS2050 |
| 13 | "Micro-Adson" anatomic forceps, delicate str., tip 0,5 mm, serrated, flat handle 150 mm, 6" total length | PRO-PZ0570 |
| 14 | "Adson" surgical forceps str., tip 1,2 mm, 1x2 teeth, flat handle 120 mm, 4 3/4" total length | PRO-PZ1051 |
| 15 | "Kelly" haemostatic forceps straight, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length | PRO-KL2330 |
| 16 | "Kocher-Ochsner" haemostatic forceps curv.,tip 2,7mm,1x2 teeth, serrated jaw 160 mm, 6 1/4" total length | PRO-KL3321 |
| 17 | "Killian" nasal specula jaw length 56 mm, tip 7,0 mm 145 mm, 5 3/4" total length | PRO-NS0410 |
| 18 | "Killian" nasal specula jaw length 75 mm, tip 7,0 mm 145 mm, 5 3/4" total length | PRO-NS0420 |
| 19 | Jansen-Middleton nose forceps 4x13mm cut 200 mm, 8" total length | PRO-NS1060 |
| 20 | Luc septum forceps fenestrated 6,0 mm, 192mm,8" total length | PRO-NS1161 |
| 21 | "Freer" elevator double en., 3,7/3,7 mm wide,sharp/blunt 185 mm, 7 1/4" total length | PRO-NS2103 |
| 22 | Nasal polyp snare knee angled 250 mm, 10" total length | PRO-NS0800 |
| 23 | "Fergusson" suction tube, curved Ø 2,0 mm = 6 Charrier 130 mm, 5 1/8" working length | PRO-SG1008 |
| 24 | "Fergusson" suction tube, curved Ø 2,5 mm = 7 Charrier 130 mm, 5 1/8" working length | PRO-SG1009 |

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 |
|-----|---|-------------|
| 25 | "Farrell" cotton applicator Ø 1,2 mm, round serrated end 140 mm, 5 1/2" total length | PRO-WT0160 |
| 26 | Mini mallet, head-Ø 20 mm lead filled, extra heavy, 80 g 165 mm, 6 1/2" total length | PRO-KN2039 |
| 27 | Bowl stainless steel capacity 0,1 L, Ø 80 mm 35 mm height | PRO-SL0990 |
| 28 | Kidney tray stainless steel capacity 0,25 L, height 37 mm 180 mm, 7 1/8" total length | PRO-SL0117 |
| 29 | Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length | PRO-NH1240 |
| 30 | "Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" total length | PRO-KL0470 |
| 31 | "Lucae" forceps, bayonet-shaped str., tip 1,5 mm, serrated, flat handle 140 mm, 5 1/2" total length | PRO-PZ1880 |
| 32 | "Buck" ear curette fig. 0, straight, blunt 150 mm, 6" total length | PRO-OR1681 |
| 33 | "Buck" ear curette fig. 1, straight, sharp 150 mm, 6" total length | PRO-OR1691 |
| 34 | Cont. 1/2 basic plus model grey bottom non-perforated 310x280x135mm | PRO-CE5503S |
| 35 | Wire basket 1/2, half size with fall handle 255x250x100 mm | PRO-ST5583 |
| 36 | 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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- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



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GA-01



BASIC ENT INSTRUMENT SET

LP: 04-09-04/0

1 pcs.

REF PRO-PZ0540

LOT 20064795



06.09.2018



Anatomic forceps, delicate str., tip 1,5 mm,
serrated, flat handle 155 mm, 6 1/8" 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

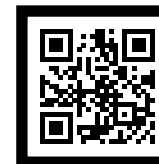
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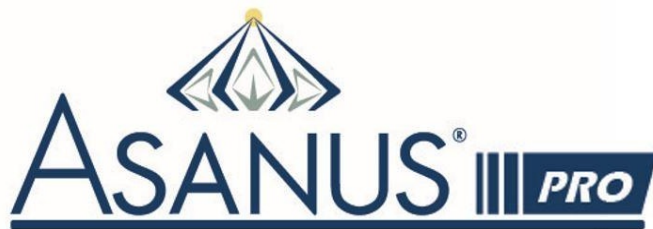
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/40



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





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GA-01



BASIC ENT INSTRUMENT SET

LP: 14-03-05/2

1 pcs.

REF PRO-KL2231

LOT 21802447

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 :

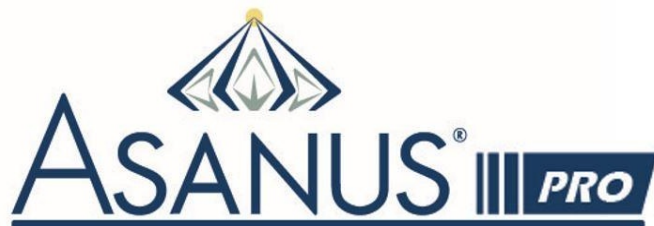
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/20



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Rx ONLY

GA-01



BASIC ENT INSTRUMENT SET

LP: 05-02-11/6

1 pcs.

REF PRO-HA0720

LOT 21803269

29.08.2018



Mouth gag "Whitehead-Jennings" 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

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



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GA-01



BASIC ENT INSTRUMENT SET

LP: 03-05-14/4

1 pcs.

REF PRO-NS1240

LOT 21901853



13.05.2019



(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



BASIC ENT INSTRUMENT SET

LP: 05-11-03/8

1 pcs.

REF PRO-KL0740

LOT 21901493



23.04.2019



"Backhaus" towel clamp 90 mm, 3 1/2" 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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Diimpor oleh :

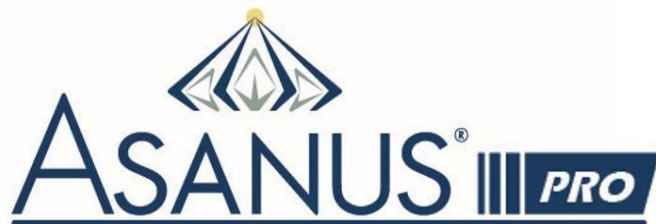
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AUF: 20192065/70



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GA01



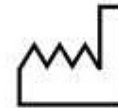
BASIC ENT INSTRUMENT SET

LP: 05-11-03/8

1 pcs.

REF PRO-SK0426

LOT 21901493



23.04.2019



Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" 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

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Diimpor oleh :
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AUF: 20192065/70



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GA-01



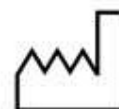
BASIC ENT INSTRUMENT SET

LP: 02-06-13/7

1 pcs.

REF PRO-NS2103

LOT 21800225



19.01.2018



"Freer" elevator double en., 3,7/3,7 mm wide, sharp/blunt 185 mm, 7 1/4" 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

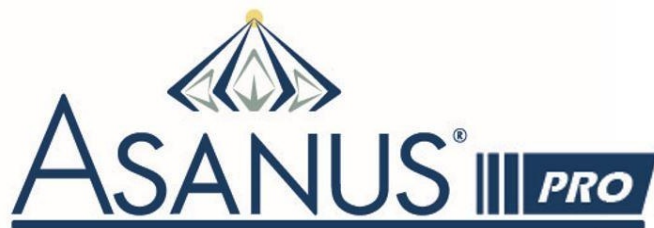
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Diimpor oleh :
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AUF: 20192065/160



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GA-01



BASIC ENT INSTRUMENT SET

LP: 04-09-04/0

1 pcs.

REF PRO-PZ0540

LOT 20064795



06.09.2018



(01)04060414086553

(10)20064795

Date: 14.10.2019

Anatomic forceps, delicate str., tip 1,5 mm,
serrated, flat handle 155 mm, 6 1/8" total length

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

Your order no.: sample labels, 14.10.2019

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AUF: 20192065/40



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GA-01



BASIC ENT INSTRUMENT SET

LP: 14-03-05/2

1 pcs.

REF PRO-OR1681

LOT 21802447

26.06.2018



(01)04060414171334

(10)21802447

Date: 14.10.2019

"Buck" ear curette fig. 0, straight, blunt 150 mm, 6" total length

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

Your order no.: sample labels, 14.10.2019

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AUF: 20192065/20



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GA-01



BASIC ENT INSTRUMENT SET

LP: 05-02-11/6

1 pcs.

REF PRO-CE5503S

LOT 21803269



29.08.2018



Cont. 1/2 basic plus model grey bottom
non-perforated 310x280x135mm

(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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GA-01



BASIC ENT INSTRUMENT SET

LP: 03-05-14/4

1 pcs.

REF PRO-ZB9094

LOT 21901853



Teflon long time filter for max.2000 cycles Ø 194 mm

13.05.2019

(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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Diimpor oleh :
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AUF: 20192065/80



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