



**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 10804026041**

Nama Dagang / Merek : **ASANUS PRO Gastrointestinal Set**  
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A  
Kategori Produk : Peralatan Gastroenterologi-Urologi  
Sub Kategori : Peralatan Gastroenterologi-Urologi Bedah  
Jenis Produk : Manual gastroenterology-urology surgical instrument and accessories.  
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, 09 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 10804026041**

No.	Deskripsi	Tipe / Kode
1	Scalpel handle No.4L for blades fig. 18-36 215 mm, 8 1/2" total length	PRO-SK0433
2	"Ultra-Cut" Mayo-Stille diss. scissors curved, 150 mm 6" total length	PRO-SC5813
3	"Nelson-Metzenbaum" dissecting scissors bl./bl., cur., tip 4,0 mm 300 mm 12" total length	PRO-SC2315
4	"DeBakey" atr. forceps, straight safety-pin with press-stopper, tip 2,0 m 240 mm, 9 1/2" total length	PRO-GF0780
5	"DeBakey" atr. forceps, str. Safety-Pin with Press-Stopper, tip 2,8mm 300 mm, 12" total length	PRO-GF0880
6	"DeBakey" atr. forceps, str. Safety-Pin with Press-Stopper, tip 3,5mm 300 mm, 12" total length	PRO-GF0888
7	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
8	Power TC needle holder a. Bozemann s-curved, tip 3,0 mm 300 mm 12" total length	PRO-NH0745
9	Needle holder a. Wangenstein, 275 mm 11" total length	PRO-NH1320
10	"Deschamp" ligature needle for right hand, blunt 210 mm, 8 1/4" total length	PRO-ND2380
11	"Deschamp" ligature needle for left hand, blunt 210 mm, 8 1/4" total length	PRO-ND2390
12	"Brunner" ligature needle slightly curved 300 mm, 12" total length	PRO-ND2500
13	"König" guiding probe 5,0 mm wide 200 mm, 8" total length	PRO-ND2620
14	"Rankin-Crile" haemostatic forceps curved, tip 2,1 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL2491
15	"Pean" haemostatic forceps straight, tip 4,1 mm, jaw length 86 mm 260 mm, 10 1/4" total length	PRO-KL3090
16	"Kocher-Ochsner" haemostatic forceps str., tip 3,4mm, 1x2 teeth, serrated jaw 200 mm, 8" total length	PRO-KL3324
17	"Overholt" dissecting forceps S-shaped, 210 mm, 8 1/4" total length	PRO-KL4080
18	"Overholt" dissecting forceps, S-shaped 215mm, 8 1/2" total length	PRO-KL4090
19	"Overholt-Geissendörfer" dissecting for. curved, tip 2,5 mm, serrated jaw 280 mm, 11 1/8" total length	PRO-KL4230
20	"Zenker" dissecting- and ligature forcep lightly curved 300 mm, 12" total length	PRO-KL4290
21	"Overholt-Mixter" dissecting forceps curved, tip 1,8 mm, serrated jaw 210 mm, 8 1/4" total length	PRO-KL4110
22	"Metzenbaum-Fino" power TC diss.scissors bl./bl., curved, very delicate shanks 230 mm 9 1/8" total length	PRO-SC0989
23	"Haberer" abdominal/intestinal spatula width of endings 37mm a. 45mm, malleable 300 mm, 12" total length	PRO-WH3099
24	"Fritsch" abdominal retractor fig. 5, blunt, blade 64x85 mm 250 mm, 10" total length	PRO-WH2770

Lampiran 1 dari 2 Halaman



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Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
25	"Doyen" vaginal specula, figure 5 blade 160x35 mm 240 mm, 9 1/2" total length	PRO-GY1135
26	Coryllos woundretractor fig.2, 115x38mm, 225mm, 9" total length	PRO-WH2300
27	"Mikulicz" abdominal retractor blunt, blade 120x50 mm 250 mm, 10" total length	PRO-WH2680
28	"Mikulicz" abdominal retractor blunt, blade 151x50 mm 250 mm, 10" total length	PRO-WH2690
29	Kidney tray stainless steel capacity 0,50 L, height 39 mm 250 mm, 10" total length	PRO-SL0125
30	"Allis" atr. intestinal grasping forceps straight, tip 6,5 mm, DeBakey teeth 200 mm, 8" total length	PRO-MD0340
31	"Allis" atr. intestinal grasping forceps mouth 8,6 mm 255 mm, 10 1/8" total length	PRO-MD0360
32	"Kocher" intestinal clamp straight, tip 6,0 mm, lengthw. serr. jaw 280 mm, 11 1/8" total length	PRO-MD0570
33	"Kocher" atraumatic intestinal clamp curved, DeBakey teeth, soft a. elastic 250 mm, 10" total length	PRO-MD0700
34	"Kocher" intestinal clamp curved, tip 6,0 mm, lengthw. serr. jaw 280 mm, 11 1/8" total length	PRO-MD0600
35	Atrauma rectal anastomoses clamp "Resano" 300 mm, 12" long	PRO-MD0950
36	Lane intestinal twin clamp straight 310 mm, 12 1/4"	PRO-MD0990
37	"Hösel" retractor blunt, blade 80x30 mm 250 mm, 10" total length	PRO-WH1920
38	Guyon atraumatic DeBakey kidney forceps, fig.1 240 mm, 9 1/2" total length	PRO-UR0100
39	Atraumatic kidney clamp "Guyon" fig.2, 230 mm, 9 1/8" total length	PRO-UR0110
40	"DeBakey-Satinsky" atr vascular clamp branche backw. curved, doub. angled 235 mm, 9 1/4" total length	PRO-GF1620
41	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
42	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
43	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, 09 Oktober 2020

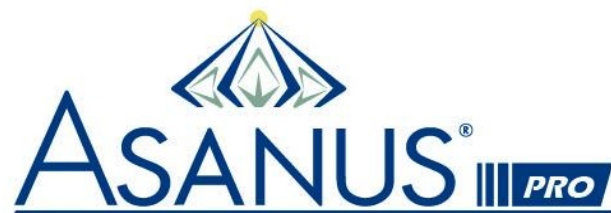


Catatan:

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Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.

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GA-01



GASTROINTESTINAL SET

LP: 10-03-03/2

1 pcs.

**REF** PRO-SK0433

**LOT** 21602426



Scalpel handle No.4L for blades fig. 18-36 215 mm,  
8 1/2" total length

10.05.2016

(01)04060414000269

(10)21602426

**Date: 15.10.2019**

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

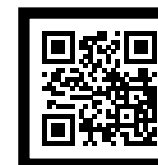
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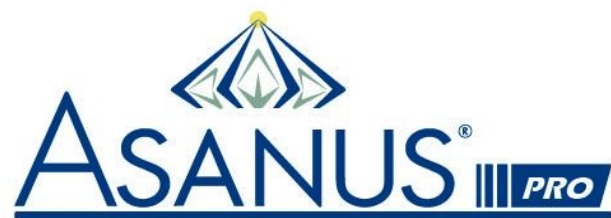
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/240**



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GA-01

GASTROINTESTINAL SET



LP: 04-09-04/0

1 pcs.

REF PRO-SC5813

LOT 20064795



"Ultra-Cut" Mayo-Stille diss. scissors curved, 150 mm 6" total length

06.09.2018

(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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Diimpor oleh :

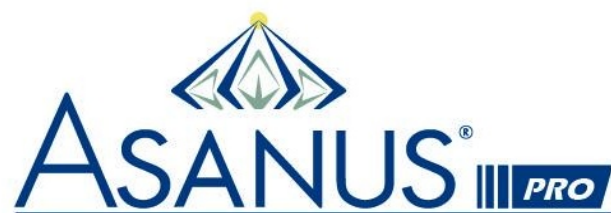
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/40



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GA-01



GASTROINTESTINAL SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-GF0780

**LOT** 21802447

26.06.2018



(01)04060414171334

(10)21802447

**Date: 14.10.2019**

"DeBakey" atr. forceps, straight safety-pin with press-stopper, tip 2,0 m 240 mm, 9 1/2" total length

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

**Your order no.: sample labels, 14.10.2019**

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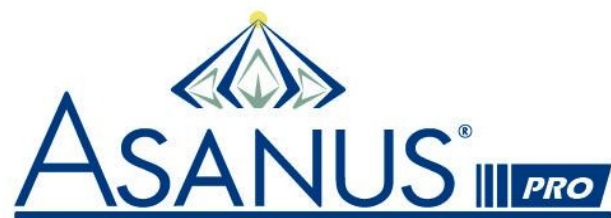
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**AUF: 20192065/20**



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GA-01



GASTROINTESTINAL SET

LP: 02-03-11/2

1 pcs.

REF PRO-NH0745

LOT 21605437



28.09.2016

Power TC needle holder a. Bozemann s-curved, tip  
3,0 mm 300 mm 12" 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

KEMENKES RI AKL.....

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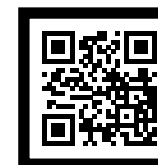
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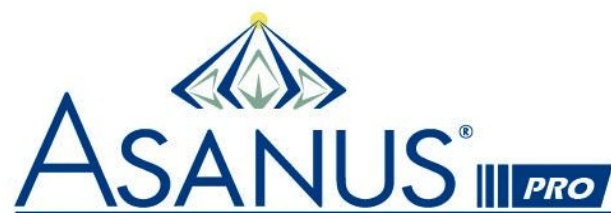
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AUF: 20192065/50



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GA-01



GASTROINTESTINAL SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-ND2380

**LOT** 21802448



26.06.2018



"Deschamp" ligature needle for right hand, blunt  
210 mm, 8 1/4" total length

(01)04060414171334

(10)21802447

**Date: 14.10.2019**

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

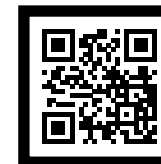
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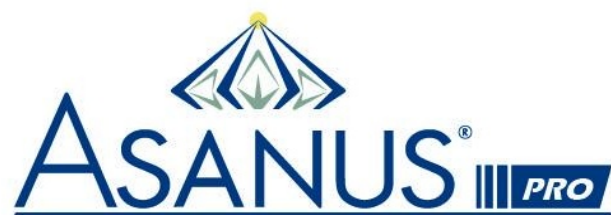
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GA-01



GASTROINTESTINAL SET

LP: 05-02-11/6

1 pcs.

REF PRO-WH2770

LOT 21803269



29.08.2018



"Fritsch" abdominal retractor fig. 5, blunt, blade 64x85 mm 250 mm, 10" total length

(01)04060414159349

(10)21803269

Date: 14.10.2019

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

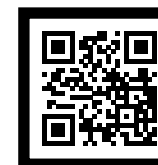
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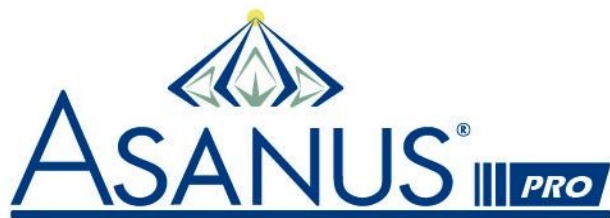
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AUF: 20192065/30



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GA-01

GASTROINTESTINAL SET

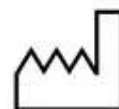
LP: 03-05-14/4

1 pcs.



**REF** PRO-GY1135

**LOT** 21901853



13.05.2019



"Doyen" vaginal specula, figure 5 blade 160x35 mm 240 mm, 9 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.....

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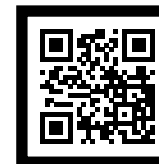
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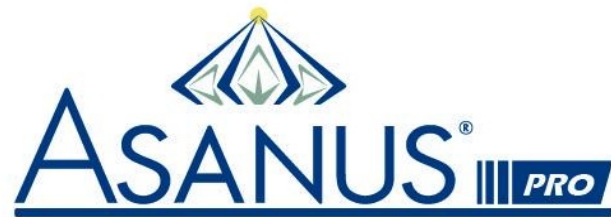
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**AUF: 20192065/80**



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GA-01



GASTROINTESTINAL SET

LP: 02-06-13/7

1 pcs.

REF PRO-MD0950

LOT 21800225

19.01.2018



Atrauma rectal anastomoses clamp "Resano" 300 mm, 12" long

(01)04060414181975

(10)21800225

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

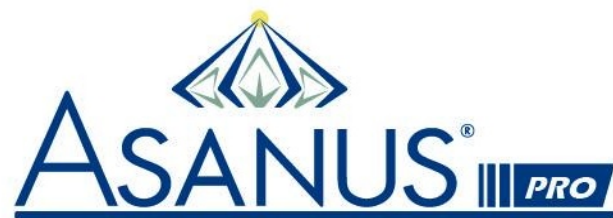
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AUF: 20192065/160



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GA01



GASTROINTESTINAL SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-UR0100

**LOT** 21901493

23.04.2019



Guyon atraumatic DeBakey kidney forceps, fig.1  
240 mm, 9 1/2" total length

(01)04060414179705

(10)21901493

**Date: 15.10.2019**

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

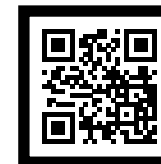
**Your order no.: sample labels, 14.10.2019**

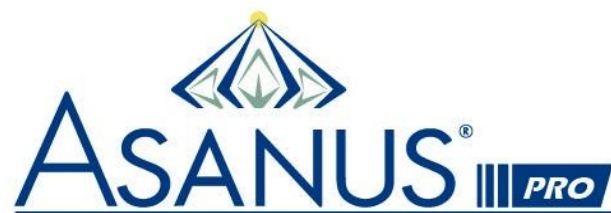
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Diproduksi oleh :  
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**AUF: 20192065/70**



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GA-01



GASTROINTESTINAL SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-CE5703S

**LOT** 20181250



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

**Your order no.: sample labels, 14.10.2019**

KEMENKES RI AKL.....

Diproduksi oleh :

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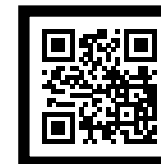
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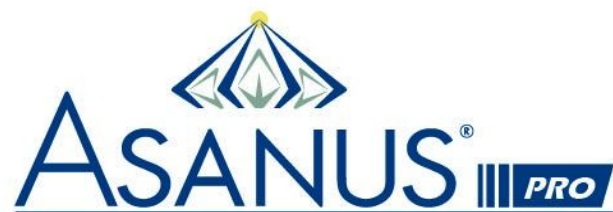
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**AUF: 20192065/20**



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GA-01

GASTROINTESTINAL SET



LP: 01-05-10/4

1 pcs.

REF PRO-ST5783

LOT 20170156

23.02.2017



(01)04060414064988

(10)20091865

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

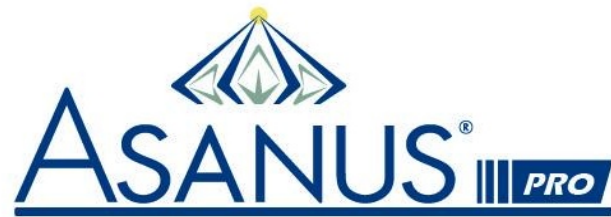
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Diproduksi oleh :  
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Diimpor oleh :  
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AUF: 20192065/100



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GA-01

GASTROINTESTINAL SET



LP: 08-03-05/5

1 pcs.

**REF** PRO-ZB9094

**LOT** 20190853



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

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**

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Diimpor oleh :  
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**AUF: 20192065/130**



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