



**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 11603025071**

Nama Dagang / Merek : **ASANUS PRO Herniotomy & Appendectomy 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, 04 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 11603025071**

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	"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL0470
4	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
5	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
6	"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" total length	PRO-SC1930
7	"Mayo" dissecting scissor curved, 140 mm 5 1/2" total length	PRO-SC1940
8	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
9	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
10	Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0204
11	Anatomic forceps, standard straight, tip 3,8 mm, serrated 180 mm, 7 1/8" total length	PRO-PZ0260
12	"Cushing" anatomic forceps str., tip 1,2 mm, serrated, fl handle 180 mm, 7 1/8" total length	PRO-PZ0640
13	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
14	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 180 mm, 7 1/8" total length	PRO-PZ1280
15	"Vaugh" surgical forceps str, tip 2,0mm,1x2 teeth, cross serrated 180 mm, 7 1/8" total length	PRO-PZ1560
16	"Allis" intestinal grasping forceps straight, tip 5,3 mm, 5x6 teeth 155 mm, 6 1/8" total length	PRO-MD0130
17	"Babcock" intestinal grasping forceps straight, tip 8,0 mm, serrated jaw 155 mm, 6 1/8" total length	PRO-MD0210
18	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230
19	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
20	"Crile" haemostatic forceps curved, tip 1,6 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2391
21	"Kelly" haemostatic forceps straight, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2330
22	"Rochester-Pean" haemostatic forceps curved, tip 3,0 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3081

Lampiran 1 dari 2 Halaman



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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
23	"Volkman" retractor 4 teeth, 8x19 mm, blunt 220 mm, 8 3/4" total length	PRO-WH1200
24	"Kelly" retractor blunt, blade 50x40 mm 260 mm, 10 1/4" total length	PRO-WH2133
25	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
26	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
27	Probe with eye tip Ø 2,5 mm, handle windowde 160 mm, 6 1/4" total length	PRO-SD0230
28	Probes straight 160 mm, 6 1/4" total length	PRO-SD0120
29	"Rochester-Ochsner" haemostatic forceps str., tip 2,4mm, 1x2 teeth, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3318
30	Bowl stainless steel capacity 0,1 L, Ø 80 mm 35 mm height	PRO-SL0990
31	Bowl stainless steel capacity 0,3 L, Ø 100 mm 65 mm height	PRO-SL0992
32	Kidney tray stainless steel capacity 0,50 L, height 39 mm 250 mm, 10" total length	PRO-SL0125
33	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
34	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
35	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, 04 September 2020

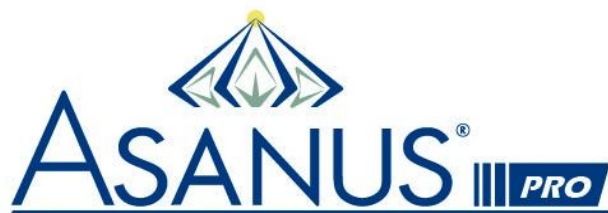


Catatan:

- 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.

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GA-01



HERNIOTOMY AND APPENDECTOMY 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

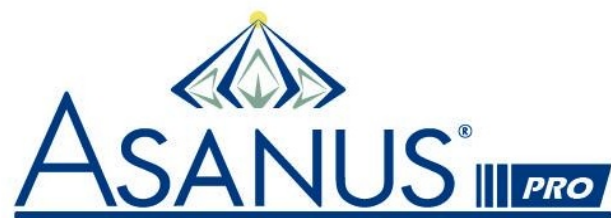
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/240**



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GA-01



HERNIOTOMY AND APPENDECTOMY 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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Diimpor oleh :

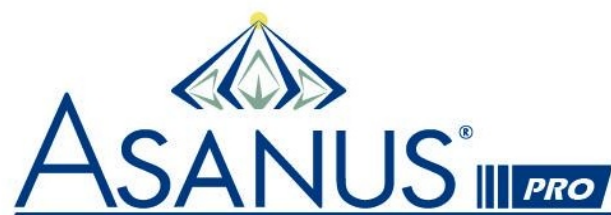
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**AUF: 20192065/40**



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GA-01



HERNIOTOMY AND APPENDECTOMY SET

LP: 14-03-05/2 1 pcs.



REF PRO-SC2305

LOT 21802447

26.06.2018



"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" 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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Diimpor oleh :

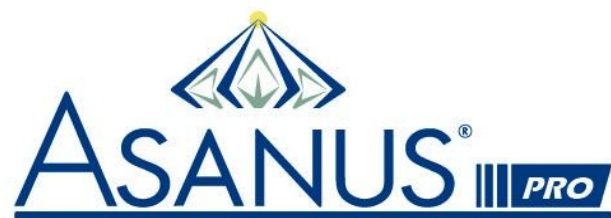
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AUF: 20192065/20



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GA-01



HERNIOTOMY AND APPENDECTOMY SET

LP: 02-03-11/2 1 pcs.

**REF** PRO-NH1230

**LOT** 21605437

28.09.2016



(01)04060414139372

(10)21605437

**Date: 14.10.2019**

"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length

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

Your order no.: sample labels, 14.10.2019

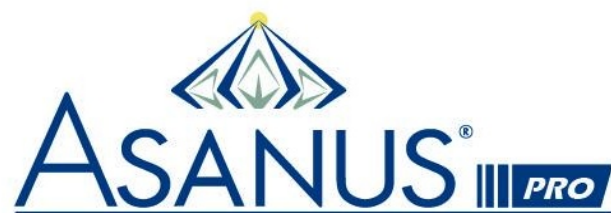
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimport oleh :  
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GA-01



HERNIOTOMY AND APPENDECTOMY SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-MD0130

**LOT** 21802448



26.06.2018



(01)04060414171334

(10)21802447

**Date: 14.10.2019**

"Allis" intestinal grasping forceps straight, tip 5,3 mm, 5x6 teeth 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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Diimpor oleh :

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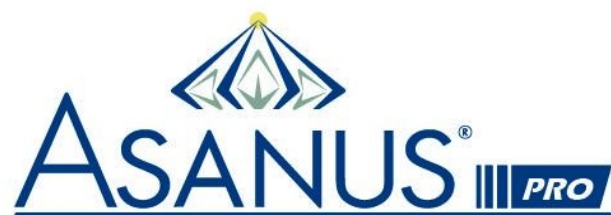
**AUF: 20192065/20**



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GA-01



HERNIOTOMY AND APPENDECTOMY SET

LP: 05-02-11/6

1 pcs.

**REF** PRO-PZ1260

**LOT** 21803269



29.08.2018



(01)04060414159349

(10)21803269

**Date: 14.10.2019**

Surgical forceps, standard str., tip 2,5 mm,  
1x2 teeth, flat handle 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.....

Diproduksi oleh :

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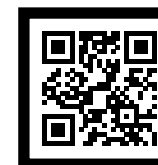
Diimpor oleh :

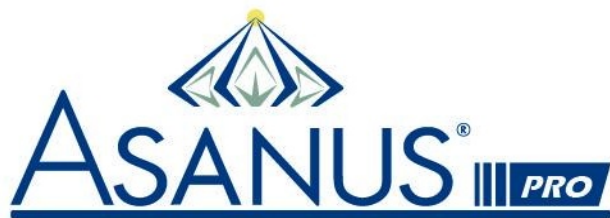
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**AUF: 20192065/30**



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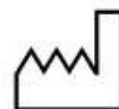
HERNIOTOMY AND APPENDECTOMY SET

LP: 03-05-14/4

1 pcs.

REF PRO-WH1200

LOT 21901853



13.05.2019



(01)04060414210095

(10)21901853

Date: 15.10.2019

"Volkman" retractor 4 teeth, 8x19 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

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Diproduksi oleh :

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Diimpor oleh :

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HERNIOTOMY AND APPENDECTOMY SET  
LP: 02-06-13/7 1 pcs.



REF PRO-SG0840

LOT 21800225

19.01.2018



(01)04060414181975  
(10)21800225

Date: 15.10.2019

"Yanka" 3 curved, Ø 10 mm  
275 mm, total length

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

Your order no.: sample labels, 14.10.2019

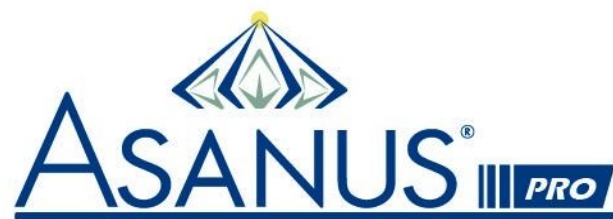
KEMENKES RI AKL.....  
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AUF: 20192065/160



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GA01



HERNIOTOMY AND APPENDECTOMY SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-SD0230

**LOT** 21901493



23.04.2019



(01)04060414179705

(10)21901493

**Date: 15.10.2019**

Probe with eye tip Ø 2,5 mm, handle windowde 160 mm, 6 1/4" 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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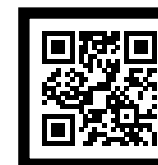
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GA-01



HERNIOTOMY AND APPENECTOMY SET

LP: 14-03-05/2

1 pcs.



**REF** PRO-SL0125

**LOT** 20181250



26.06.2018



Kidney tray stainless steel capacity 0,50 L,  
height 39 mm 250 mm, 10" 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.....

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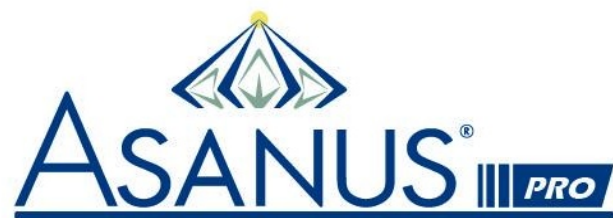
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HERNIOTOMY AND APPENDECTOMY SET

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

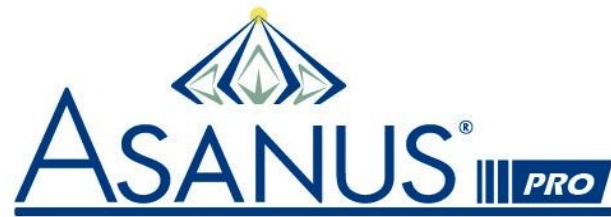
KEMENKES RI AKL.....  
Diproduksi oleh :  
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Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/100



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GA-01



HERNIOTOMY AND APPENDECTOMY 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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Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

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HERNIOTOMY AND APPENDECTOMY 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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Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/150**



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