



**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 11103025515**

Nama Dagang / Merek : **ASANUS PRO Hysterectomy Set**  
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A  
Kategori Produk : Peralatan Obstetrik dan Ginekologi  
Sub Kategori : Peralatan Obstetrik dan Ginekologi Bedah  
Jenis Produk : Obstetric-gynecologic general manual 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, 22 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 11103025515**

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	Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0204
4	Anatomic forceps, standard straight, tip 3,8 mm, serrated 180 mm, 7 1/8" total length	PRO-PZ0260
5	Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 8" total length	PRO-PZ0270
6	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
7	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 200 mm, 8" total length	PRO-PZ1290
8	"Semken" anatomic forceps, delicate str., tip 1,0 mm, serrated, flat handle 150 mm, 6" total length	PRO-PZ0530
9	"Semken" surgical forceps str., tip 1,0 mm, 1x2 teeth, flat handle 150 mm, 6" total length	PRO-PZ1530
10	Surgical scissors bl./bl., str., tip 7,2 mm 145 mm 5 3/4" total length	PRO-SC1462
11	Dissecting scissors a. Mayo, curved, 155 mm 6 1/8" total length	PRO-SC1941
12	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
13	"Siebold" classic uterine scissors S - shaped, 245 mm 9 3/4" total length	PRO-SC2975
14	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
15	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
16	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
17	"Kocher" retractor 4-teeth, sharp, blade 15x20 mm 220 mm, 8 3/4" total length	PRO-WH1290
18	Woundretractor Mayo-Collins,double 31x16mm & 21x14mm, 28x16mm&17x14mm 2pcs=set, 150 mm 6" total length	PRO-WH0200
19	"Doyen" vaginal specula, figure 2 blade 90x60 mm 240 mm, 9 1/2" total length	PRO-GY1180
20	"Kelly" retractor blunt, blade 64x54 mm 260 mm, 10 1/4" total length	PRO-WH2130
21	"Pean" haemostatic forceps, delicate straight, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3030
22	"Pean" haemostatic forceps curved, tip 2,5 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3079
23	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230

Lampiran 1 dari 3 Halaman



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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No.	Deskripsi	Tipe / Kode
24	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
25	"Kocher-Ochsner" haemostatic forceps str., tip 3,0 mm, 1x2 teeth, serrated jaw 185 mm, 7 1/4" total length	PRO-KL3322
26	"Rochester-Pean" haemostatic forceps curved, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3085
27	"Mikulicz" peritoneum forceps curved, tip 3,5 mm, serrated jaw 180 mm, 7 1/8" total length	PRO-KL4570
28	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
29	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
30	"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL0470
31	"Babcock" intestinal grasping forceps straight, tip 9,7 mm, serrated jaw 215 mm, 8 1/2" total length	PRO-MD0230
32	"Allis-Adair" intest.-/tissue gras. forc. mouth 10,5 mm, 10x11 teeth 155 mm, 6 1/8" total length	PRO-MD0104
33	"Wertheim" scissors for gynecology bl./bl., curved 230 mm 9 1/8" total length	PRO-SC2852
34	"Schröder" uterine tenaculum forceps sharp, fine pattern 250 mm, 10" total length	PRO-GY2540
35	"Doyen" myoma screw 170 mm, 6 3/4" total length	PRO-GY2930
36	"Heaney" hysterectomy forceps curved, tip 3,8 mm, serrated jaw 205 mm, 8 1/8" total length	PRO-KL4780
37	"Wiener Modell" hysterectomy forceps 240 mm, 9 1/2" long	PRO-KL4820
38	Atraumatic hysterectomy forceps "Heaney" straight 225mm 9" long	PRO-KL4830
39	"Heaney" atraumatic hysterectomy forceps strongly curved 215mm, 8 1/2" total length	PRO-KL4850
40	"Kocher-Ochsner" haemostatic forceps str., tip 3,7mm, 1x2 teeth, serrated jaw 225 mm, 9" total length	PRO-KL3326
41	"Rochester-Pean" haemostatic forceps curved, tip 3,5 mm, serrated jaw 225 mm, 9" total length	PRO-KL3087
42	Bowl stainless steel capacity 0,1 L, Ø 80 mm 35 mm height	PRO-SL0990
43	Bowl stainless steel capacity 0,3 L, Ø 100 mm 65 mm height	PRO-SL0992
44	Kidney tray stainless steel capacity 0,25 L, height 37 mm 180 mm, 7 1/8" total length	PRO-SL0117
45	Kidney tray stainless steel capacity 0,50 L, height 39 mm 250 mm, 10" total length	PRO-SL0125
46	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
47	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
48	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

Lampiran 2 dari 3 Halaman



Catatan:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

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Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
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Jakarta, 22 September 2020

	<b>KEMENTERIAN KESEHATAN REPUBLIK INDONESIA</b>	Ditandatangani Secara Elektronik Oleh : a.n Direktur Jenderal Direktur Penilaian Alat Kesehatan dan PKRT  Dr. IGM. Wirabrata, Apt NIP. 19751206 200312 1 001
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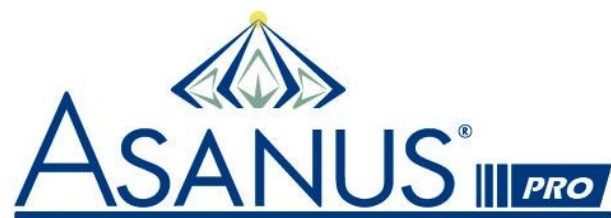


Catatan:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

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GA-01



HYSTERECTOMY 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**

KEMENKES RI AKL.....

Diproduksi oleh :

ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany

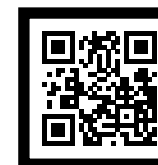
Diimpor oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/40**



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GA-01



HYSTERECTOMY SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-SK0426

**LOT** 21802447

26.06.2018



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

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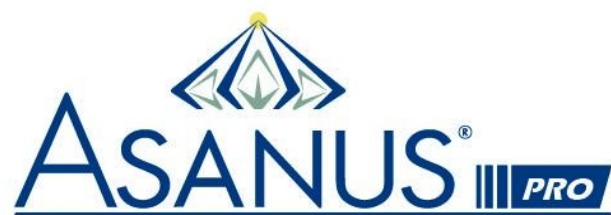
**AUF: 20192065/20**



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Rx ONLY

GA-01



HYSTERECTOMY SET

LP: 05-02-11/6

1 pcs.

**REF** PRO-PZ0260

**LOT** 21803269

29.08.2018



Anatomic forceps, standard straight, tip 3,8 mm, serrated 180 mm, 7 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

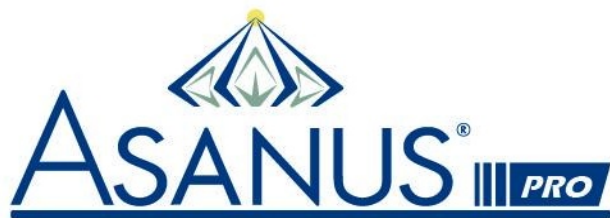
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GA-01



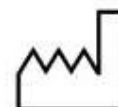
HYSTERECTOMY SET

LP: 03-05-14/4

1 pcs.

REF PRO-SC1462

LOT 21901853



13.05.2019



Surgical scissors bl./bl., str., tip 7,2 mm 145 mm 5 3/4" 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.....

Diproduksi oleh :

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Diimpor oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

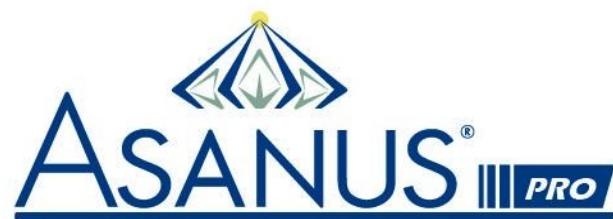
AUF: 20192065/80



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GA01



HYSTERECTOMY SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-NH1230

**LOT** 21901493



23.04.2019



(01)04060414179705

(10)21901493

**Date: 15.10.2019**

"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

Diimpor oleh :

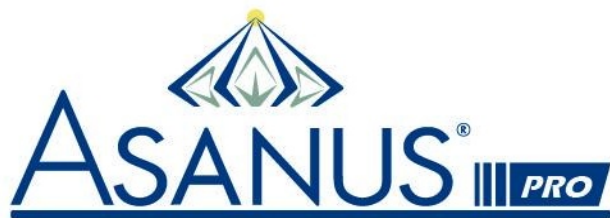
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**AUF: 20192065/70**



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GA-01



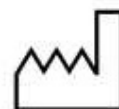
HYSTERECTOMY SET

LP: 03-05-14/4

1 pcs.

REF PRO-WH0200

LOT 21901853



13.05.2019



Woundretractor Mayo-Collins, double  
31x16mm & 21x14mm, 28x16mm&17x14mm  
2pcs=set, 150 mm 6" total length

(01)04060414210095

(10)21901853

Date: 15.10.2019

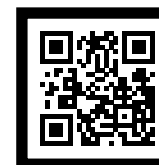
Cust.-No.: 13098 ID ASANUS INDONES/ PT. ASANUS

Your order no.: sample labels, 14.10.2019

AUF: 20192065/80



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GA-01



HYSTERECTOMY SET

LP: 01-05-10/4

1 pcs.

**REF** PRO-MD0230

**LOT** 20091865

23.02.2017



(01)04060414064988

(10)20091865

**Date: 15.10.2019**

"Babcock" intestinal grasping forceps straight,  
tip 9,7 mm, serrated jaw 215 mm, 8 1/2" total  
length

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

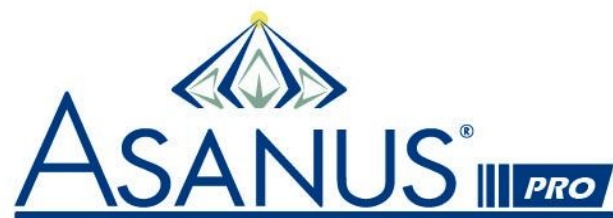
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AUF: 20192065/100



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GA-01



HYSTERECTOMY 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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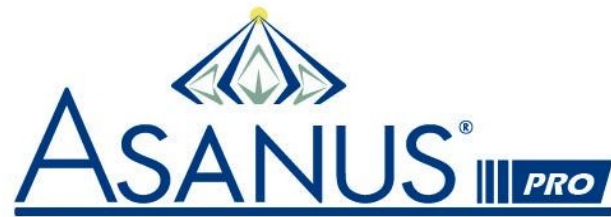
AUF: 20192065/100



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GA-01



HYSTERECTOMY SET

LP: 08-03-05/5

1 pcs.

**REF** PRO-ST5783

**LOT** 20190853

24.04.2019



Wire basket 1/2, half size with fall handle  
255x250x100 mm

(01)04060414203707

(10)21901531

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



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GA-01



HYSTERECTOMY 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**

KEMENKES RI AKL.....  
Diproduksi oleh :  
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**AUF: 20192065/150**



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