



**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 11103025164**

Nama Dagang / Merek : **ASANUS PRO General Laparatomy for Gynecology 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, 09 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 11103025164**

No.	Deskripsi	Tipe / Kode
1	Scalpel handle No.4, short for blades fig. 18-36 135 mm, 5 1/4" total length	PRO-SK0432
2	Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
3	Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 210 mm, 8 1/4" total length	PRO-SK0427
4	"Deaver" surgical scissors bl./bl., curved, 145 mm 5 3/4" total length	PRO-SC1850
5	"Mayo" dissecting scissors straight 155 mm 6 1/8" total length	PRO-SC1931
6	Dissecting scissors a. Mayo, curved, 155 mm 6 1/8" total length	PRO-SC1941
7	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
8	"Wertheim" scissors for gynecology bl./bl., curved 200 mm 8" total length	PRO-SC2851
9	"Sims" gynecology scissors bl./bl., curved, 200 mm 8" total length	PRO-SC2940
10	Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0204
11	"Cushing" anatomic forceps str., tip 1,4 mm, serrated, fl handle 200 mm, 8" total length	PRO-PZ0650
12	Anatomic forceps, standard straight, tip 4,5 mm, serrated 250 mm, 10" total length	PRO-PZ0280
13	Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 8" total length	PRO-PZ0270
14	Surgical forceps, standard str., tip 3,4 mm, 1x2 teeth, flat handle 250 mm, 10" total length	PRO-PZ1300
15	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 200 mm, 8" total length	PRO-PZ1290
16	Surgical forceps str., tip 3,3 mm, 2x3 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1330
17	"Foerster" sponge-/dressing forceps straight, smooth jaw 245 mm, 9 3/4" total length	PRO-KL0450
18	"Backhaus" towel clamp curved, tip 1,7 mm, sharp 135 mm, 5 1/4" total length	PRO-KL0760
19	"Kelly" haemostatic forceps curved, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL2331
20	"Rochester-Pean" haemostatic forceps curved, tip 3,0 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3081
21	"Rochester-Pean" haemostatic forceps curved, tip 3,2 mm, serrated jaw 185 mm, 7 1/4" total length	PRO-KL3083
22	"Rochester-Pean" haemostatic forceps curved, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3085
23	"Kocher-Ochsner" haemostatic forceps str., tip 3,4mm,1x2 teeth, serrated jaw 200 mm, 8" total length	PRO-KL3324

Lampiran 1 dari 2 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.

- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



**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



No.	Deskripsi	Tipe / Kode
24	"Leriche" haemostatic forceps straight, tip 1,6 mm, 1x2 teeth 150 mm, 6" total length	PRO-KL2520
25	Lahey gall ductus clamp 225mm. 9" total length	PRO-KL4350
26	"Mikulicz" peritoneum forceps curv.,tip 4,1 mm,1x2 teeth, serrated jaw 205 mm, 8 1/8" total length	PRO-KL4610
27	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
28	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
29	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
30	"Deaver" retractor fig.4, 50 mm wide 310 mm, 12 1/4" total length	PRO-WH2570
31	"Kelly" retractor blunt, blade 70x65 mm 260 mm, 10 1/4" total length	PRO-WH2140
32	"Kocher" retractor blunt, blade 80x60 mm 250 mm, 10" total length	PRO-WH2030
33	"Richardson" retractor blunt, blade 47x21 mm 240 mm, 9 1/2" total length	PRO-WH2120
34	"Balfour" abdominal retractor lat. blade 65mm deep, mid. blade 47x80 m	PRO-WH6160
35	"Babcock" intestinal grasping forceps straight, tip 8,0 mm, serrated jaw 155 mm, 6 1/8" total length	PRO-MD0210
36	"Allis" intestinal grasping forceps straight, tip 5,3 mm, 5x6 teeth 155 mm, 6 1/8" total length	PRO-MD0130
37	Catheter for women, metal Charr. 16 160 mm, 6 1/4" total length	PRO-UR0456
38	"Kristeller" set vaginal specula 90x36 mm, upper & lower blade 175 mm, 7" total length	PRO-GY0570
39	"Teale" uterine tenaculum forceps 3x4 teeth, angled to side 225 mm, 9" total length	PRO-GY2690
40	"Sommer" uterine elevating forceps curved 235 mm, 9 1/4" total length	PRO-GY2900
41	"Doyen" myoma screw 190 mm, 7 1/2" total length	PRO-GY2940
42	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
43	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
44	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
45	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 September 2020

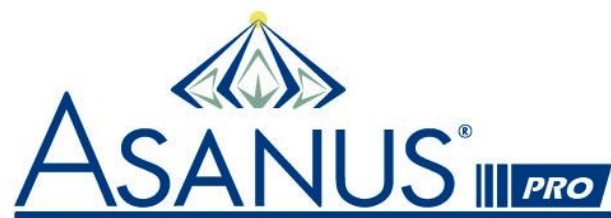


Catatan:

- 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.



www.asanus.de

GA-01



Rx ONLY

GENERAL LAPARATOMY FOR GYNAECOLOGY 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 :

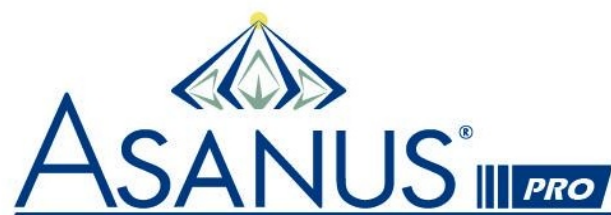
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/40



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





www.asanus.de

GA-01



GENERAL LAPARATOMY FOR GYNAECOLOGY SET



LP: 14-03-05/2

1 pcs.

**REF** PRO-GY0570

**LOT** 21802447



26.06.2018



"Kristeller" set vaginal specula 90x36 mm,  
upper & lower blade 175 mm, 7" 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.....

Diproduksi oleh :

ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany

Diimpor oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

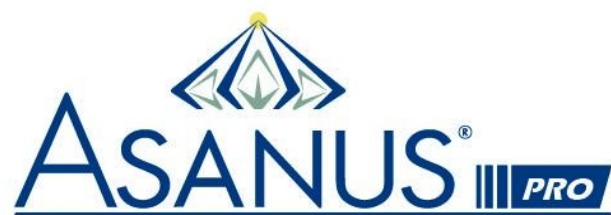
**AUF: 20192065/20**



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







www.asanus.de

GA-01



Rx ONLY

GENERAL LAPARATOMY FOR GYNAECOLOGY SET



LP: 05-02-11/6

1 pcs.

REF PRO-PZ0270

LOT 21803269



29.08.2018



Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 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

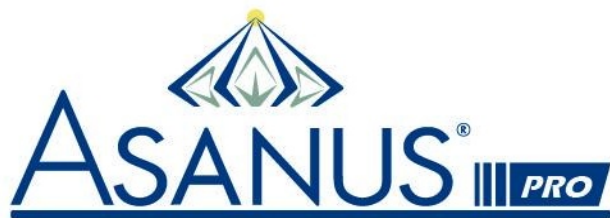
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/30



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





www.asanus.de



GA-01



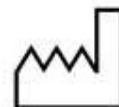
GENERAL LAPARATOMY FOR GYNAECOLOGY SET

LP: 03-05-14/4

1 pcs.

**REF** PRO-WH2570

**LOT** 21901853



13.05.2019



(01)04060414210095

(10)21901853

**Date: 15.10.2019**

"Deaver" retractor fig.4, 50 mm wide 310 mm, 12 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 :

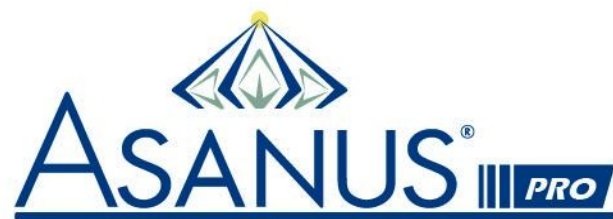
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/80**



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





www.asanus.de



GA01



GENERAL LAPARATOMY FOR GYNAECOLOGY SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-SG0840

**LOT** 21901493



23.04.2019



(01)04060414179705

(10)21901493

**Date: 15.10.2019**

"Yankauer" suction tube curved, Ø 10 mm  
275 mm, 11" 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: 20192065/70**



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







www.asanus.de

GA-01



GENERAL LAPARATOMY FOR GYNAECOLOGY 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**

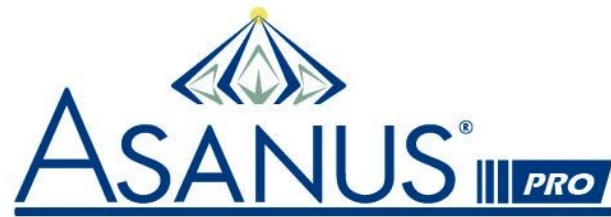
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/100**



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





www.asanus.de

GA-01



Rx ONLY

GENERAL LAPARATOMY FOR GYNAECOLOGY 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

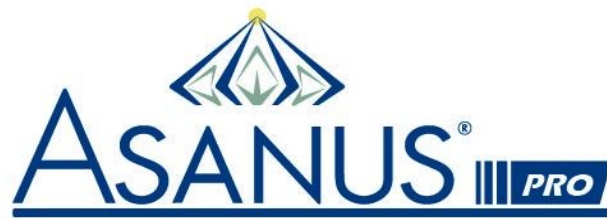
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/130



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





www.asanus.de

GA-01



Rx ONLY

GENERAL LAPARATOMY FOR GYNAECOLOGY 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 :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/150



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

