



**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 11103025791**

Nama Dagang / Merek : **ASANUS PRO Major Vaginal 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, 05 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 11103025791**

No.	Deskripsi	Tipe / Kode
1	Bowl stainless steel capacity 0,1 L, Ø 80 mm 35 mm height	PRO-SL0990
2	Bowl stainless steel capacity 0,3 L, Ø 100 mm 65 mm height	PRO-SL0992
3	"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" total length	PRO-KL0470
4	Kidney tray stainless steel capacity 0,50 L, height 39 mm 250 mm, 10" total length	PRO-SL0125
5	Scalpel handle No.3, str. ,mirror finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
6	Scalpel handle No.4, short for blades fig. 18-36 135 mm, 5 1/4" total length	PRO-SK0432
7	Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0204
8	Anatomic forceps, standard straight, tip 3,8 mm, serrated 180 mm, 7 1/8" total length	PRO-PZ0260
9	Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 8" total length	PRO-PZ0270
10	"Cushing" anatomic forceps str., tip 1,2 mm, serrated, fl handle 180 mm, 7 1/8" total length	PRO-PZ0640
11	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
12	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 180 mm, 7 1/8" total length	PRO-PZ1280
13	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 200 mm, 8" total length	PRO-PZ1290
14	"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" total length	PRO-SC1930
15	"Mayo" dissecting scissor curved, 140 mm 5 1/2" total length	PRO-SC1940
16	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
17	"Nelson-Metzenbaum" dissecting scissors bl./bl., cur., tip 4,0 mm 230 mm, 9 1/8" total length	PRO-SC2309
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	"Pean" haemostatic forceps, delicate straight, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3030
21	"Pean" haemostatic forceps curved, tip 2,5 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3079
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 3,0 mm, 1x2 teeth, serrated jaw 185 mm, 7 1/4" total length	PRO-KL3322

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	"Yankauer" suction tube curved, Ø 10 mm 275 mm, 11" total length	PRO-SG0840
25	"Allis" intestinal grasping forceps straight, tip 5,3 mm, 5x6 teeth 155 mm, 6 1/8" total length	PRO-MD0130
26	"Siebold" classic uterine scissors S - shaped, 245 mm 9 3/4" total length	PRO-SC2975
27	"Heaney" hysterectomy forceps curved, tip 3,8 mm, serrated jaw 205 mm, 8 1/8" total length	PRO-KL4780
28	"Bozemann" uterine dressing forceps s-shape 250 mm, 10" total length	PRO-GY2460
29	"Schröder" uterine tenaculum forceps sharp, fine pattern 250 mm, 10" total length	PRO-GY2540
30	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
31	"Kallmorgen" vaginal specula 75X39mm 170 mm 63/4" total length	PRO-GY0870
32	Schroeder forceps 250 mm, 10" long, isolated at the working area	PRO-GY2542I
33	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
34	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
35	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
36	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
37	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, 05 Oktober 2020

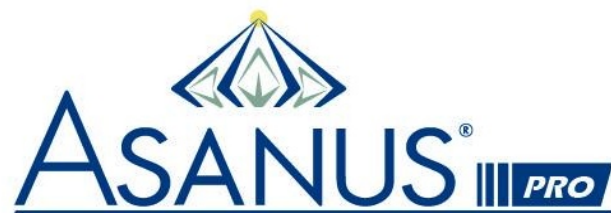


Catatan:

- 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.



www.asanus.de



GA-01



MAJOR VAGINAL SET

LP: 10-03-03/2

1 pcs.

**REF** PRO-SK0426

**LOT** 21602426

10.05.2016



(01)04060414000269

(10)21602426

**Date: 15.10.2019**

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

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

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

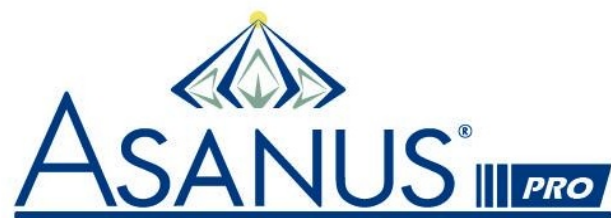
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/240**



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





www.asanus.de



GA-01



MAJOR VAGINAL SET

LP: 04-09-04/0

1 pcs.

REF PRO-KL0470

LOT 20064795



06.09.2018



"Foerster" sponge-/dressing forceps straight, tip 13,0 mm, serrated jaw 245 mm, 9 3/4" 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 :

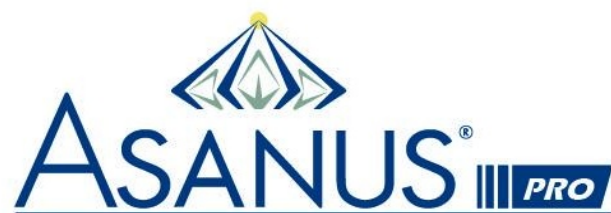
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/40



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





www.asanus.de



GA-01



MAJOR VAGINAL SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-PZ0204

**LOT** 21802447

26.06.2018



Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" 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 :

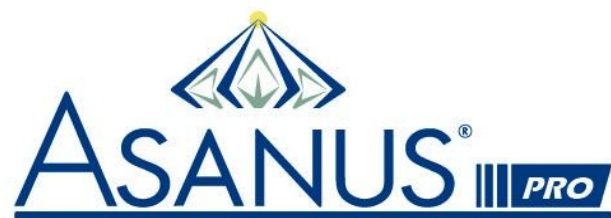
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/20**



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





www.asanus.de



Rx ONLY

GA-01



MAJOR VAGINAL SET

LP: 02-03-11/2

1 pcs.

**REF** PRO-NH1240

**LOT** 21605437

28.09.2016



(01)04060414139372

(10)21605437

**Date: 14.10.2019**

Needle holder a. Hegar - Mayo droite,  
185mm 185 mm, 7 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: 20192065/50**



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





www.asanus.de



Rx ONLY

GA-01



MAJOR VAGINAL SET

LP: 05-02-11/6

1 pcs.

REF PRO-KL2230

LOT 21803269

29.08.2018



(01)04060414159349

(10)21803269

Date: 14.10.2019

"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" 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: 20192065/30



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







www.asanus.de



Rx ONLY

GA-01



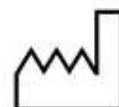
MAJOR VAGINAL SET

LP: 03-05-14/4

1 pcs.

REF PRO-WH0320

LOT 21901853



13.05.2019



"US-Army" retractor, double ended 1 set,  
22x15 / 39x15mm, 26x15 / 43x15mm 220  
mm, 8 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 :  
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



GA-01



MAJOR VAGINAL 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**

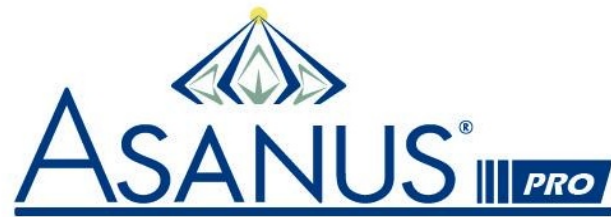
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/100**



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





www.asanus.de



GA-01



MAJOR VAGINAL 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



MAJOR VAGINAL 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

