



**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 11603025516**

Nama Dagang / Merek : **ASANUS PRO Laparotomy Instrument 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, 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 11603025516**

No.	Deskripsi	Tipe / Kode
1	Scalpel handle No.7, mirror finsh. for blades fig. 10-15, 40, 42 160 mm, 6 1/4" total length	PRO-SK0428
2	Scalpel handle No.4, short for blades fig. 18-36 135 mm, 5 1/4" total length	PRO-SK0432
3	Scalpel handle No.3, str. ,mirror finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
4	"Metzenbaum" dissecting scissor bl./bl., cur., tip 3,1 mm 200 mm, 8" total length	PRO-SC2307
5	"Nelson-Metzenbaum" dissecting scissors bl./bl., cur., tip 4,0 mm 230 mm, 9 1/8" total length	PRO-SC2309
6	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
7	"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" total length	PRO-SC1930
8	"Mayo" dissecting scissor curved, 140 mm 5 1/2" total length	PRO-SC1940
9	Anatomic forceps, standard straight, tip 1,8 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0204
10	Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 8" total length	PRO-PZ0270
11	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
12	"Gerald" surgical forceps str., tip 1,4 mm, 1x2 teeth, flat handle 175 mm, 7" total length	PRO-PZ1480
13	"Maier" sponge-/dressing forceps without lock, curved 265 mm, 10 1/2" total length	PRO-KL0270
14	"Backhaus" towel clamp curved, tip 1,5 mm, sharp 110 mm, 4 1/4" total length	PRO-KL0750
15	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230
16	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
17	"Halsted" haemostatic forceps straight, tip 1,7 mm, serrated jaw 185 mm, 7 1/4" total length	PRO-KL2620
18	"Halsted" haemostatic forceps str., tip 2,2mm,1x2 teeth, serrated jaw 185 mm, 7 1/4" total length	PRO-KL2690
19	"Pean" haemostatic forceps, delicate straight, tip 2,0 mm, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3030
20	"Rochester-Pean" haemostatic forceps straight, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3084
21	"Rochester-Pean" haemostatic forceps straight, tip 3,7 mm, serrated jaw 240 mm, 9 1/2" total length	PRO-KL3088
22	"Rochester-Ochsner" haemostatic forceps str., tip 2,4mm,1x2 teeth, serrated jaw 140 mm, 5 1/2" total length	PRO-KL3318

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.

- 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
23	"Kocher-Ochsner" haemostatic forceps str., tip 3,4mm,1x2 teeth, serrated jaw 200 mm, 8" total length	PRO-KL3324
24	"Overholt-Geissendörfer" dissecting for. curved, tip 2,4 mm, serrated jaw 220 mm, 8 3/4" total length	PRO-KL4160
25	"Overholt-Geissendörfer" dissecting for. curved, tip 2,0 mm, serrated jaw 210 mm, 8 1/4" total length	PRO-KL4130
26	"Mikulicz" peritoneum forceps curved, tip 3,5 mm, serrated jaw 180 mm, 7 1/8" total length	PRO-KL4570
27	Inner case for needle case set PRO-ND0850 perforated Ø 65 mm	PRO-ND0852
28	Needle holder a. Wangensteen, 275 mm 11" total length	PRO-NH1320
29	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
30	Needle holder a. Hegar - Mayo droite, 185mm 185 mm, 7 1/4" total length	PRO-NH1240
31	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
32	"Deschamp" ligature needle for right hand, blunt 210 mm, 8 1/4" total length	PRO-ND2380
33	"Nelaton" probe curved, blunt 160 mm, 6 1/4" total length	PRO-SD0140
34	Myrtle leaf probe tip Ø 2,0 mm 145 mm, 5 3/4" total length	PRO-SD0270
35	"Roux" retractor, double ended 1 set/3 pieces (PRO-WH0250/PRO-WH0260/PRO-WH0270) 165 mm, 6 1/2" total length	PRO-WH0240
36	"Roux" retractor, double ended 19x22 / 23x30 mm 145 mm, 5 3/4" total length	PRO-WH0250
37	Roux woundretractor double ended 155mm, 6 1/8" total length	PRO-WH0260
38	Roux hook woundretractor double , big 165mm, 6 1/2" total length	PRO-WH0270
39	"Volkman" retractor 6 teeth, 8,5x29 mm, semi-sharp 220 mm, 8 3/4" total length	PRO-WH1260
40	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
41	"Mikulicz" abdominal retractor blunt, blade 120x50 mm 250 mm, 10" total length	PRO-WH2680
42	"Haberer" abdominal/intestinal spatula width of endings 37mm a. 45mm, malleable 300 mm, 12" total length	PRO-WH3099
43	"Allis" atr. intestinal grasping forceps straight, tip 6,5 mm, DeBaKey teeth 200 mm, 8" total length	PRO-MD0340
44	"Duval" lung grasping forceps 21 mm wide 230 mm, 9 1/8" total length	PRO-GF3639
45	Kidney tray stainless steel capacity 0,50 L, height 39 mm 250 mm, 10" total length	PRO-SL0125
46	Laboratory bowl, heavy-weight model B4, capacity 0,16 L, Ø 85 mm 40 mm height	PRO-SL1006
47	Laboratory bowl, heavy-weight model B6, capacity 0,4 L, Ø 110 mm 55 mm height	PRO-SL1008
48	Abdominal retractor Balfour, lateral blades 65mm depth, center blade 65x80 mm	PRO-WH6180

Lampiran 2 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.

- 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
49	Abdominal retractor Balfour, lateral blades 100 mm depth, center blade 80x80 spreading 250 mm	PRO-WH6200
50	Kirschner abdominal retractor complete, with holding frame PRO-WH6500 and	PRO-WH6490
51	Kirschner frame alone 250x250 mm	PRO-WH6500
52	Blade alone for PRO-WH6470 frame	PRO-WH6540
53	Blade alone 50X65mm for Kirschner retractor frame	PRO-WH6530
54	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
55	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
56	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, 22 September 2020

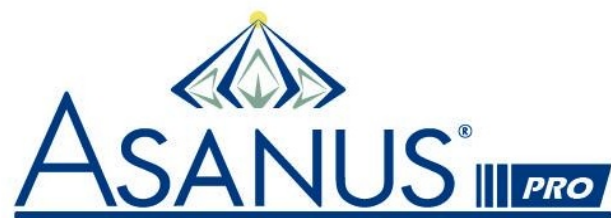


Catatan:

- 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.



www.asanus.de



GA-01



LAPAROTOMY INSTRUMENT 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 :

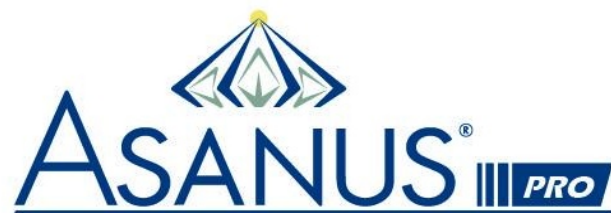
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/40**



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





www.asanus.de



GA-01



LAPAROTOMY INSTRUMENT SET

LP: 14-03-05/2

1 pcs.

**REF** PRO-SC2307

**LOT** 21802447

26.06.2018



"Metzenbaum" dissecting scissor bl./bl., cur., tip 3,1 mm 200 mm, 8" total length

(01)04060414171334

(10)21802447

**Date: 14.10.2019**

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

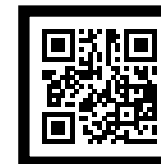
**Your order no.: sample labels, 14.10.2019**

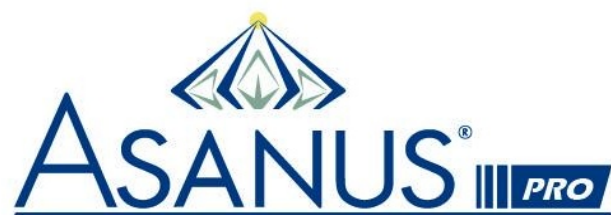
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/20**



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





www.asanus.de



Rx ONLY

GA-01



LAPAROTOMY INSTRUMENT 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 :

ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany

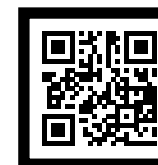
Diimpor oleh :

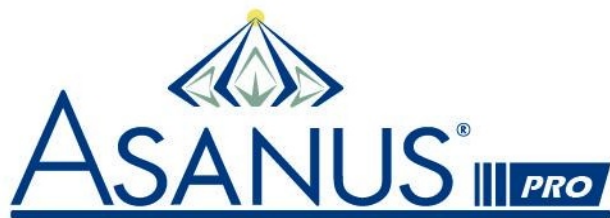
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**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



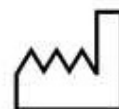
LAPAROTOMY INSTRUMENT SET

LP: 03-05-14/4

1 pcs.

REF PRO-KL3084

LOT 21901853



13.05.2019



(01)04060414210095

(10)21901853

Date: 15.10.2019

"Rochester-Pean" haemostatic forceps straight, tip 3,2 mm, serrated jaw 200 mm, 8" 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

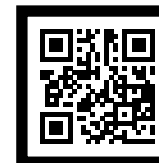
Diimpor oleh :

PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

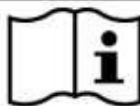
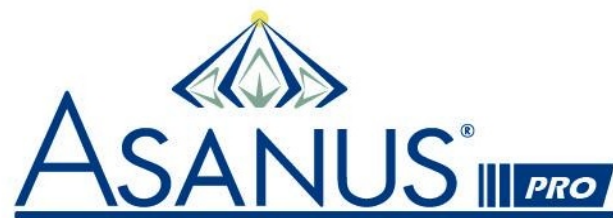
AUF: 20192065/80



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







www.asanus.de



GA01



LAPAROTOMY INSTRUMENT SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-NH1240

**LOT** 21901493



23.04.2019



Needle holder a. Hegar - Mayo droite,  
185mm 185 mm, 7 1/4" total length

(01)04060414179705

(10)21901493

**Date: 15.10.2019**

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

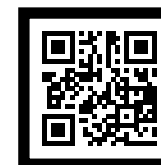
**Your order no.: sample labels, 14.10.2019**

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



GA01



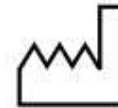
LAPAROTOMY INSTRUMENT SET

LP: 05-11-03/8

1 pcs.

**REF** PRO-SD0140

**LOT** 21901493



23.04.2019



"Nelaton" probe curved, bluntt 160 mm, 6  
1/4" 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**

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

**AUF: 20192065/70**

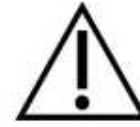


ASANUS Medizintechnik GmbH, take-off Gewerbepark 2, D-78579 Neuhausen obEck, info@asanus.de





www.asanus.de



GA-01



LAPAROTOMY INSTRUMENT SET

LP: 08-01-04/4

1 pcs.

**REF** PRO-WH0260

**LOT** 21505072

29.10.2015



(01)04060414152876

(10)21505072

**Date: 15.10.2019**

Roux woundretractor double ended  
155mm, 6 1/8" total length

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

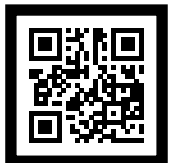
**Your order no.: sample labels, 14.10.2019**

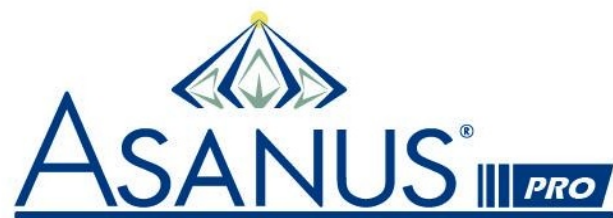
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

**AUF: 20192065/190**



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





www.asanus.de



Rx ONLY

GA-01



LAPAROTOMY INSTRUMENT SET

LP: 01-05-10/4

1 pcs.

REF PRO-CE5703S

LOT 20170156

23.02.2017



(01)04060414064988

(10)20091865

Date: 15.10.2019

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

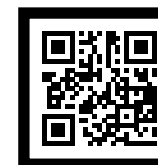
Your order no.: sample labels, 14.10.2019

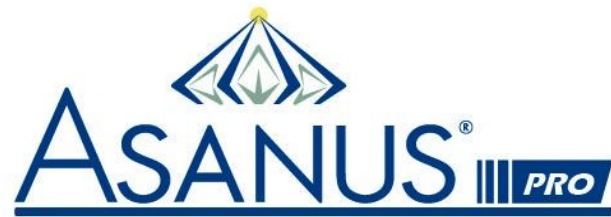
KEMENKES RI AKL.....  
Diproduksi oleh :  
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany  
Diimpor oleh :  
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/100



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





www.asanus.de



GA-01



LAPAROTOMY INSTRUMENT SET

LP: 08-03-05/5

1 pcs.

**REF** PRO-ST5783

**LOT** 20190853

24.04.2019



Wire basket 1/1, full size, with fall handle  
480x250x100 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.....  
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



LAPAROTOMY INSTRUMENT 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

