



**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 10804026049

Nama Dagang / Merek : **ASANUS PRO Abdominal Operation Set**
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A
Kategori Produk : Peralatan Gastroenterologi-Urologi
Sub Kategori : Peralatan Gastroenterologi-Urologi Bedah
Jenis Produk : Manual gastroenterology-urology surgical instrument and accessories.
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 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 10804026049**

No.	Deskripsi	Tipe / Kode
1	"Duval" lung grasping forceps 14 mm wide 230 mm, 9 1/8" total length	PRO-GF3638
2	"Yankauer" suction tube, gebogen tip-Ø10 mm, hole Ø4,8mm, olive Ø6-10 mm 270 mm, 10 3/4" total length	PRO-HA2070
3	"Maier" sponge-/dressing forceps without lock, curved 265 mm, 10 1/2" total length	PRO-KL0270
4	"Backhaus" towel clamp curved, tip 1,5 mm, sharp 110 mm, 4 1/4" total length	PRO-KL0750
5	"Halsted-Mosquito" haemostatic forceps straight, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2230
6	"Halsted-Mosquito" haemostatic forceps curved, tip 1,0 mm, serrated jaw 125 mm, 5" total length	PRO-KL2231
7	"Adson" haemostatic forceps straight, tip 1,5 mm, serrated jaw 185 mm, 7 1/4" total length	PRO-KL2600
8	"Rochester-Pean" haemostatic forceps straight, tip 3,0 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3080
9	"Rochester-Pean" haemostatic forceps curved, tip 3,0 mm, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3081
10	"Rochester-Pean" haemostatic forceps straight, tip 3,2 mm, serrated jaw 200 mm, 8" total length	PRO-KL3084
11	"Kocher-Ochsner" haemostatic forceps str., tip 2,7mm,1x2 teeth, serrated jaw 160 mm, 6 1/4" total length	PRO-KL3320
12	"Kocher-Ochsner" haemostatic forceps str., tip 3,4mm,1x2 teeth, serrated jaw 200 mm, 8" total length	PRO-KL3324
13	"Overholt-Geissendörfer" dissecting forc curved, tip 1,8 mm, serrated jaw 195 mm, 7 3/4" total length	PRO-KL4120
14	"Overholt-Geissendörfer" dissecting for. curved, tip 2,0 mm, serrated jaw 210 mm, 8 1/4" total length	PRO-KL4130
15	"Overholt-Geissendörfer" dissecting for. curved, tip 2,3 mm, serrated jaw 220 mm, 8 3/4" total length	PRO-KL4140
16	"Mikulicz" peritoneum forceps curved, tip 3,5 mm, serrated jaw 180 mm, 7 1/8" total length	PRO-KL4570
17	"Baby-Allis" intestinal grasping forceps straight, tip 5,8 mm, cross-serrated jaw 155 mm, 6 1/8" total length	PRO-MD0111
18	"Allis" intestinal grasping forceps straight, tip 5,7 mm, 5x6 teeth 190 mm, 7 1/2" total length	PRO-MD0140
19	Needle case round, consisting of 1 outer case and 1 inner case perforated width 17 mm, Ø 65 mm	PRO-ND0850
20	"Mayo-Hegar" needle holder straight, tip 2,0 mm, needle size 2-6 mm 150 mm, 6" total length	PRO-NH1230
21	"Mayo-Hegar" needle holder straight, tip 2,5 mm, needle size 2-6 mm 200 mm, 8" total length	PRO-NH1250
22	Needle holder a. Wangenstein, 275 mm 11" total length	PRO-NH1320

Lampiran 1 dari 3 Halaman



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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
23	Anatomic forceps, standard straight, tip 3,2 mm, serrated 145 mm, 5 3/4" total length	PRO-PZ0240
24	Anatomic forceps, standard straight, tip 4,0 mm, serrated 200 mm, 8" total length	PRO-PZ0270
25	"Potts-Smith" surgical forceps str., tip 1,5 mm, serrated, flat handle 180 mm, 7 1/8" total length	PRO-PZ0362
26	Surgical forceps, standard str., tip 2,5 mm, 1x2 teeth, flat handle 145 mm, 5 3/4" total length	PRO-PZ1260
27	Surgical forceps, standard str., tip 3,0 mm, 1x2 teeth, flat handle 200 mm, 8" total length	PRO-PZ1290
28	"Gerald" surgical forceps str., tip 1,4 mm, 1x2 teeth, flat handle 175 mm, 7" total length	PRO-PZ1480
29	"Potts-Smith" surgical forceps str., tip 1,5 mm, 1x2 teeth, serrated 185 mm, 7 1/4" total length	PRO-PZ1542
30	"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" total length	PRO-SC1930
31	"Mayo" dissecting scissor curved, 140 mm 5 1/2" total length	PRO-SC1940
32	"Metzenbaum" dissecting scissors bl./bl., cur., tip 2,8 mm 180 mm, 7 1/8" total length	PRO-SC2305
33	"Nelson-Metzenbaum" dissecting scissors bl./bl., cur., tip 4,0 mm 230 mm, 9 1/8" total length	PRO-SC2309
34	"Nelaton" probe curved, blunt 160 mm, 6 1/4" total length	PRO-SD0140
35	Scalpel handle No.3, str. ,mirrow finsh. for blades fig. 10-15, 40, 42 125 mm, 5" total length	PRO-SK0426
36	Scalpel handle No.7, mirrow finsh. for blades fig. 10-15, 40, 42 160 mm, 6 1/4" total length	PRO-SK0428
37	Scalpel handle No.4, short for blades fig. 18-36 135 mm, 5 1/4" total length	PRO-SK0432
38	Kidney tray stainless steel capacity 0,50 L, height 39 mm 250 mm, 10" total length	PRO-SL0125
39	Laboratory bowl, heavy-weight model B4, capacity 0,16 L, Ø 85 mm 40 mm height	PRO-SL1006
40	Laboratory bowl, heavy-weight model B6, capacity 0,4 L, Ø 110 mm 55 mm height	PRO-SL1008
41	"Roux" retractor, double ended 1 set/3 pieces (PRO-WH0250/PRO-WH0260/PRO-WH0270) 165 mm, 6 1/2" total length	PRO-WH0240
42	"US-Army" retractor, double ended 1 set, 22x15 / 39x15mm, 26x15 / 43x15mm 220 mm, 8 3/4" total length	PRO-WH0320
43	Cushing wound retractor fig. 2, blunt, 1 blade 9x10 mm 200 mm, 8" total length	PRO-WH0848
44	"Volkman" retractor 2 prongs, semi-sharp 225mm, 9" total length	PRO-WH1035
45	"Kocher-Langenbeck" retractor blunt, blade 55x11 mm 215 mm, 8 1/2" total length	PRO-WH1700
46	"Mikulicz" abdominal retractor blunt, blade 120x50 mm 250 mm, 10" total length	PRO-WH2680
47	"Fritsch" abdominal retractor fig. 4, blunt, blade 45x75 mm 250 mm, 10" total length	PRO-WH2760

Lampiran 2 dari 3 Halaman



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Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
48	"Haberer" abdominal/intestinal spatula width of endings 37mm a. 45mm, malleable 300 mm, 12" total length	PRO-WH3099
49	"Balfour" abdominal retractor lat. blade 65mm deep, mid. blade 47x80 mm	PRO-WH6160
50	Abdominal retractor Balfour, lateral blades 65mm depth, center blade 65x80 mm	PRO-WH6180
51	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
52	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
53	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 Oktober 2020

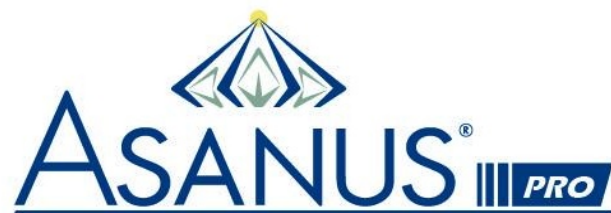


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- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

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GA-01



ABDOMINAL OPERATION SET

LP: 10-03-03/2

1 pcs.

REF PRO-GF3638

LOT 21602426



"Duval" lung grasping forceps 14 mm wide 230 mm, 9 1/8" total length

10.05.2016

(01)04060414000269
(10)21602426

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

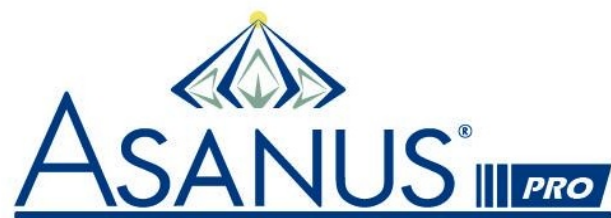
KEMENKES RI AKL.....
Diproduksi oleh :
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany
Diimpor oleh :
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/240



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





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GA-01



ABDOMINAL OPERATION SET

LP: 04-09-04/0

1 pcs.

REF PRO-HA2070

LOT 20064795

06.09.2018



(01)04060414086553

(10)20064795

Date: 14.10.2019

"Yankauer" suction tube, gebogen tip-Ø10 mm, hole Ø4,8mm, olive Ø6-10 mm 270 mm, 10 3/4" total length

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

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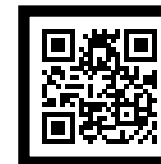
Diimpor oleh :

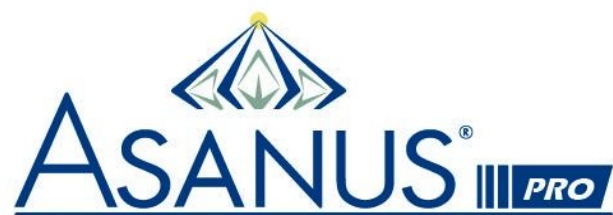
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/40



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GA-01



ABDOMINAL OPERATION SET

LP: 14-03-05/2

1 pcs.



REF PRO-KL0750

LOT 21802447



26.06.2018



"Backhaus" towel clamp curved, tip 1,5 mm, sharp 110 mm, 4 1/4" 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 :

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Diimpor oleh :

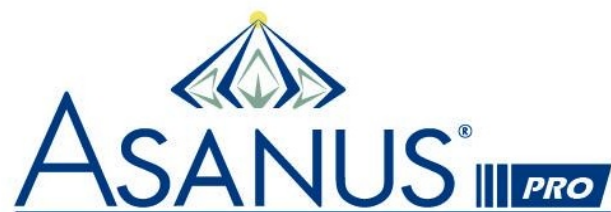
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AUF: 20192065/20



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GA-01

ABDOMINAL OPERATION SET



LP: 02-03-11/2

1 pcs.

REF PRO-NH1230

LOT 21605437

28.09.2016



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

(01)04060414139372

(10)21605437

Date: 14.10.2019

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

Your order no.: sample labels, 14.10.2019

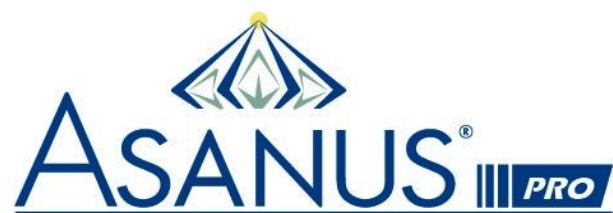
KEMENKES RI AKL.....
Diproduksi oleh :
ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany
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AUF: 20192065/50



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GA-01



ABDOMINAL OPERATION SET

LP: 14-03-05/2

1 pcs.

REF PRO-KL4120

LOT 21802448



26.06.2018



(01)04060414171334

(10)21802447

Date: 14.10.2019

"Overholt-Geissendörfer" dissecting forceps curved, tip 1,8 mm, serrated jaw 195 mm, 7 3/4" total length

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 :

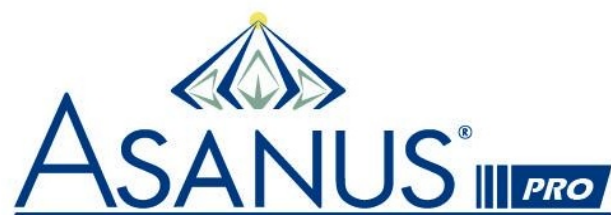
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/20



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GA-01



ABDOMINAL OPERATION 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



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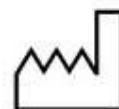
ABDOMINAL OPERATION SET

LP: 03-05-14/4

1 pcs.

REF PRO-ND0850

LOT 21901853



13.05.2019



Needle case round, consisting of 1 outer case and 1 inner case perforated width 17 mm, Ø 65 mm

(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.....

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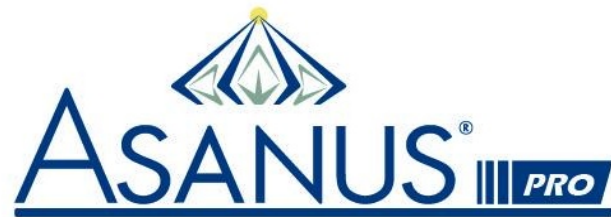
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AUF: 20192065/80



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GA-01



ABDOMINAL OPERATION SET

LP: 02-06-13/7

1 pcs.

REF PRO-SC1930

LOT 21800225

19.01.2018



"Mayo" dissecting scissors bl./bl., str., tip 2,4 mm 140 mm, 5 1/2" total length

(01)04060414181975

(10)21800225

Date: 15.10.2019

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

Your order no.: sample labels, 14.10.2019

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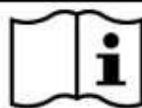
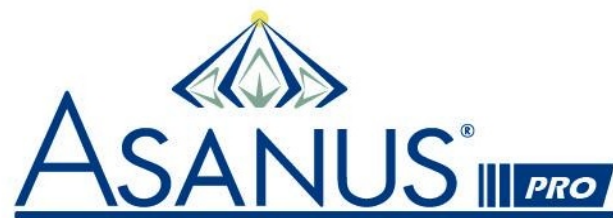
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AUF: 20192065/160



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GA01



ABDOMINAL OPERATION 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

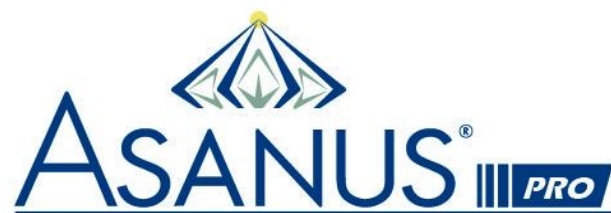
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Diimpor oleh :
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AUF: 20192065/70



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GA-01



ABDOMINAL OPERATION SET

LP: 14-03-05/2

1 pcs.



REF PRO-SK0426

LOT 20181250



26.06.2018



(01)04060414171334

(10)21802447

Date: 14.10.2019

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

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Diproduksi oleh :

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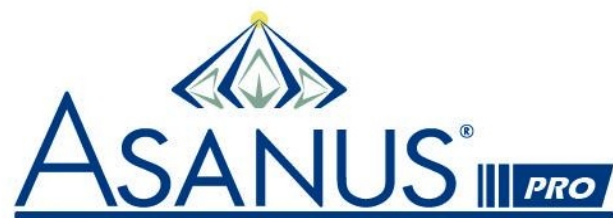
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AUF: 20192065/20



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GA-01



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ABDOMINAL OPERATION SET

LP: 01-05-10/4

1 pcs.



REF PRO-WH1035

LOT 20170156

23.02.2017



(01)04060414064988

(10)20091865

Date: 15.10.2019

"Volkmann" retractor 2 prongs, semi-sharp
225mm, 9" total length

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



ABDOMINAL OPERATION SET

LP: 08-03-05/5

1 pcs.

REF PRO-CE5703S

LOT 20190853

24.04.2019



(01)04060414203707

(10)21901531

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

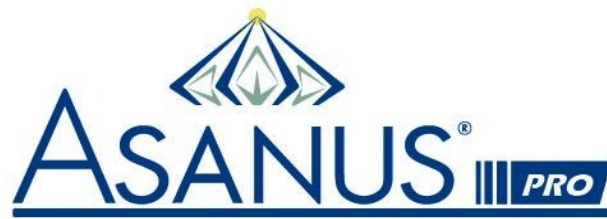
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GA-01



ABDOMINAL OPERATION 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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