



**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 10703026941

Nama Dagang / Merek : **ASANUS PRO Rhinoplasty Set**
Kelompok / Kelas Resiko : Non Elektromedik Non Steril / A
Kategori Produk : Peralatan Telinga, Hidung dan Tenggorokan
Sub Kategori : Peralatan Telinga, Hidung dan Tenggorokan Bedah
Jenis Produk : Ear, nose, and throat manual surgical 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, 12 November 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 10703026941**

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	"Masing" cartilage slitting knife curved in the tip 130 mm, 5 1/8" total length	PRO-NS1960
3	"Cottle-Masing" gingival scissors sh./sh., curved, 105 mm 4 1/8" total length	PRO-SC0809
4	"Cottle-Knapp" nasal scissors curved, blunt/blunt, tip 1,3 mm 105 mm, 4 1/8" total length	PRO-NS0970
5	"Fomon" nasal scissors strongly curved, tip 2,4 mm 135 mm, 5 1/4" total length	PRO-NS1011
6	"Cottle" nose scissors blunt/blunt 165 mm, 6 1/2" total length	PRO-NS0990
7	"Joseph" delicate scissors sh./sh., curved, 150 mm 6" total length	PRO-SC0571
8	"Cottle" nasal forceps, bayonet-shaped with screw fixation, tip 2,0 mm 140 mm, 5 1/2" total length	PRO-NS1880
9	"Adson-Brown" surgical forceps str., tip 2,2 mm, 9x9 teeth, flat handle 120 mm, 4 3/4" total length	PRO-PZ1640
10	"Gruenwald" forceps, bayonet-shaped str., tip 2,0 mm, serrated, flat handle 200 mm, 8" total length	PRO-PZ1910
11	"Converse" power TC needle holder straight, tip 1,2mm, needle size 5-6 mm 130 mm, 5 1/8" total length	PRO-NH0180
12	"Lathbury-Farrell" cotton applicator Ø 1,2 mm, triangular serrated end 160 mm, 6 1/4" total length	PRO-WT0190
13	"Cottle" alar retractor blunt, 1 blade 10x12 mm 140 mm, 5 1/2" total length	PRO-NS2290
14	"Cottle" skin retractor 1 prong 160 mm, 6 1/4" total length	PRO-NS3030
15	"Fomon" nasal retractor blunt/blunt 145 mm, 5 3/4" total length	PRO-NS2230
16	"Aufricht" nasal etractor double angled, tip 7,0 mm 160 mm, 6 1/4" total length	PRO-NS0530
17	"Cottle" nasal specula jaw length 90 mm, tip 7,0 mm 135 mm, 5 1/4" total length	PRO-NS0480
18	"Cottle" nasal specula jaw length 76 mm, tip 7,0 mm 135 mm, 5 1/4" total length	PRO-NS0470
19	"Cottle" nasal specula jaw length 105 mm, tip 7,0 mm 135 mm, 5 1/4" total length	PRO-NS0485
20	"Cottle septum chisel straight, 4,0 mm wide 180 mm, 7 1/8" total length	PRO-NS2460
21	"Cottle septum chisel straight, 7,0 mm wide 180 mm, 7 1/8" total length	PRO-NS2470
22	"Cottle septum chisel straight, 9,0 mm wide 180 mm, 7 1/8" total length	PRO-NS2480
23	"Cottle septum chisel straight, 12,0 mm wide 180 mm, 7 1/8" total length	PRO-NS2490

Lampiran 1 dari 2 Halaman



Catatan:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

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



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DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN

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Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
24	"Cottle septum chisel curved, 6,0 mm wide, graduated 180 mm, 7 1/8" total length	PRO-NS2500
25	"Masing" osteotome curved to the left 175 mm, 7 " total length	PRO-NS2580
26	"Masing" osteotome curved to the right 175 mm, 7 " total length	PRO-NS2590
27	"MC Kenty" septum raspatory 3,0 mm wide, sharp 145 mm, 5 3/4" total length	PRO-NS2180
28	"Joseph" periost raspatory 2,9 mm wide 165 mm, 6 1/2" total length	PRO-KN0760
29	"Fergusson"suction tube, curved Ø 2,5 mm=7 charrier 110 mm, 4 1/4 working length	PRO-SG0792
30	"Fergusson"suction tube, curved Ø 3,0 mm=9 charrier 110 mm, 4 1/4 working length	PRO-SG0793
31	"Fomon" double file fine/coarde, 6,5 mm / 7,5 mm 215 mm, 8 1/2" total length	PRO-NS2740
32	"Fomon" durogrip rasp 6,5 / 7,5 mm, fine/coarse teeth 215 mm, 8 1/2" total length	PRO-NS2750
33	Bone and cartilage Crusher with clamp for taking out the prep.mat. 65 mm, 2 1/2" total length	PRO-NS2900
34	"Blakesley" nasal forceps str., figure 2, mouth 10x4,2 mm 110 mm, 4 1/4" length of shaft	PRO-NS1230
35	"Watson-Williams" ethmoid forceps serrated 120 mm, 4 3/4" total length	PRO-NS1330
36	"Jansen-Middleton" nasal forceps intersected 210 mm, 8 1/4" total length	PRO-NS1070
37	"Joseph" nasal saw bayonet-shaped, curved to the right 190 mm, 7 1/2" total length	PRO-NS2890
38	Cont. 1/1 basic plus model grey bottom non-perforated 600x285x135mm	PRO-CE5703S
39	Wire basket 1/1, full size, with fall handle 480x250x100 mm	PRO-ST5783
40	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, 12 November 2020



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R_X ONLY

GA-01



RHINOPLASTY SET

LP: 04-09-04/0

1 pcs.

REF PRO-PZ1640

LOT 20064795

06.09.2018



(01)04060414086553

(10)20064795

Date: 14.10.2019

"Adson-Brown" surgical forceps str., tip 2,2 mm, 9x9 teeth, flat handle 120 mm, 4 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: 20192065/40



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





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GA-01



RHINOPLASTY SET

LP: 14-03-05/2

1 pcs.

REF PRO-NS1960

LOT 21802447

26.06.2018



"Masing" cartilage slitting knife curved in the tip 130 mm, 5 1/8" total length

(01)04060414171334

(10)21802447

Date: 14.10.2019

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

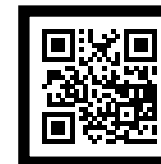
Your order no.: sample labels, 14.10.2019

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

AUF: 20192065/20



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GA-01



RHINOPLASTY SET

LP: 05-02-11/6

1 pcs.

REF PRO-SK0426

LOT 21803269



29.08.2018



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



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GA-01



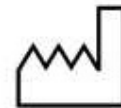
RHINOPLASTY SET

LP: 03-05-14/4

1 pcs.

REF PRO-PZ1640

LOT 21901853



13.05.2019



"Adson-Brown" surgical forceps str., tip 2,2 mm, 9x9 teeth, flat handle 120 mm, 4 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

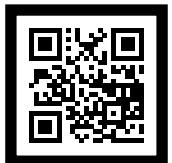
Diimpor oleh :

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AUF: 20192065/80



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GA01



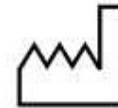
RHINOPLASTY SET

LP: 05-11-03/8

1 pcs.

REF PRO-NH0180

LOT 21901493



23.04.2019



"Converse" power TC needle holder straight, tip 1,2mm,
needle size 5-6 mm 130 mm, 5 1/8" 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 :
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Diimpor oleh :
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AUF: 20192065/70



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GA01



RHINOPLASTY SET

LP: 05-11-03/8

1 pcs.

REF PRO-NS2230

LOT 21901493



"Fomon" nasal retractor blunt/blunt 145 mm, 5 3/4" total length

23.04.2019

(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 :
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AUF: 20192065/70



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Rx ONLY

GA-01



1 pcs.

RHINOPLASTY SET

LP: 02-06-13/7

REF PRO-NS0480

LOT 21800225



19.01.2018

"Cottle" nasal specula jaw length 90 mm, tip 7,0 mm 135 mm, 5 1/4" 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

KEMENKES RI AKL.....

Diproduksi oleh :

ASANUS MEDIZINTECHNIK GmbH, Neuhausen - Germany

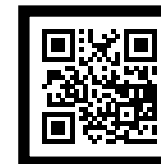
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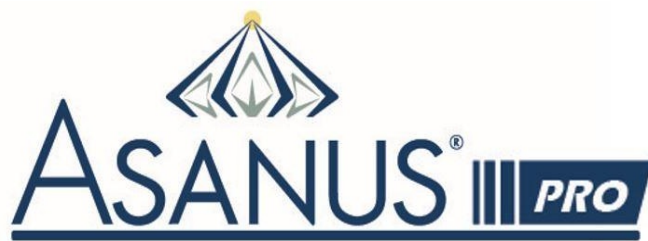
PT ASANUS MEDIKA INDONESIA, Banten - Indonesia

AUF: 20192065/160



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Rx ONLY

GA-01



RHINOPLASTY SET

LP: 04-09-04/0

1 pcs.

REF PRO-NS2460

LOT 20064795



06.09.2018



"Cottle septum chisel straight, 4,0 mm wide 180 mm, 7 1/8" 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 :

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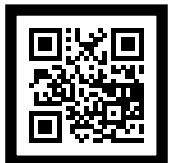
Diimpor oleh :

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AUF: 20192065/40



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GA-01



RHINOPLASTY SET

LP: 14-03-05/2

1 pcs.

REF PRO-NS2180

LOT 21802447

26.06.2018



(01)04060414171334

(10)21802447

Date: 14.10.2019

"MC Kenty" septum raspatory 3,0 mm wide, sharp 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.....

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AUF: 20192065/20



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GA-01



RHINOPLASTY SET

LP: 05-02-11/6

1 pcs.

REF PRO-CE5703S

LOT 21803269



29.08.2018



Cont. 1/1 basic plus model grey bottom non-perforated
600x285x135mm

(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

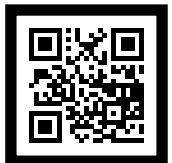
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AUF: 20192065/30



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Rx ONLY

GA-01



RHINOPLASTY SET

LP: 03-05-14/4

1 pcs.

REF PRO-ZB9094

LOT 21901853



13.05.2019



Teflon long time filter for max.2000 cycles Ø 194 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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