



PEMERINTAH REPUBLIK INDONESIA

PERIZINAN BERUSAHA UNTUK MENUNJANG KEGIATAN USAHA IZIN EDAR ALAT KESEHATAN IMPOR PB-UMKU: 812000277198600090016

Pemerintah Republik Indonesia menerbitkan Perizinan Berusaha Untuk Menunjang Kegiatan Usaha (PB-UMKU), yang merupakan Izin edar alat kesehatan impor kepada Pelaku Usaha berikut ini:

- | | |
|--|--|
| 1. Nama Pelaku Usaha | : PT RAJAWALI MEDIKA MANDIRI |
| 2. Nomor Induk Berusaha (NIB) | : 8120002771986 |
| 3. Alamat Kantor | : Jl. Rajawali Sakti, Komp. Rajawali Sakti Permai B. 22-23, Desa/Kelurahan
Dungus Cariang, Kec. Andir, Kota Bandung, Provinsi Jawa Barat
Kode Pos: 40183 |
| 4. Status Penanaman Modal | : Penanaman Modal Dalam Negeri (PMDN) |
| 5. Kode Klasifikasi Baku Lapangan Usaha Indonesia (KBLI) | : 46691 - Perdagangan Besar Alat Laboratorium, Alat Farmasi Dan Alat
Kedokteran Untuk Manusia |
| 6. Lokasi Usaha | : Jl. Rajawali Sakti Komp. Rajawali Sakti Permai B. 22-23 Desa/Kelurahan
Dungus Cariang, Kec. Andir, Kota Bandung, Provinsi Jawa Barat
Kode Pos: 40183 |

Telah memenuhi persyaratan:

1. Persyaratan Administrasi

Lampiran Perizinan Berusaha Untuk Menunjang Kegiatan Usaha ini memuat data teknis yang merupakan bagian tidak terpisahkan dari dokumen ini. Pelaku Usaha tersebut di atas wajib menjalankan kegiatan usahanya sesuai dengan ketentuan perundang-undangan yang berlaku.

Diterbitkan tanggal: 30 April 2024

a.n. Menteri Kesehatan
Menteri Investasi/
Kepala Badan Koordinasi Penanaman Modal,



Ditandatangani secara elektronik

Dicetak tanggal: 30 April 2024

1. Dokumen ini diterbitkan sistem OSS berdasarkan data dari Pelaku Usaha, tersimpan dalam sistem OSS, yang menjadi tanggung jawab Pelaku Usaha.
2. Dalam hal terjadi kekeliruan isi dokumen ini akan dilakukan perbaikan sebagaimana mestinya.
3. Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan oleh BSR-E-BSSN.
4. Data lengkap Perizinan Berusaha dapat diperoleh melalui sistem OSS menggunakan hak akses.





PEMERINTAH REPUBLIK INDONESIA

PERIZINAN BERUSAHA UNTUK MENUNJANG KEGIATAN USAHA
LAMPIRAN
IZIN EDAR ALAT KESEHATAN IMPOR
PB-UMKU : 812000277198600090016

Lampiran berikut memuat data teknis Izin Edar Alat Kesehatan Impor, sebagai berikut:

KEMENKES RI AKL 21501420256

Nama Dagang / Merek : **EUROCOLUMBUS Alien X Mobile C-Arm Unit**
Kelompok / Kelas Resiko : Elektromedik Radiasi / C
Kategori Produk : Peralatan Radiologi
Sub Kategori : Peralatan Radiologi Diagnostik
Jenis Produk : Image-intensified fluoroscopic x-ray system.
Tipe / Ukuran : Alien X
Kemasan : Unit
Nama Produsen / Pabrikan : EUROCOLUMBUS S.R.L, Italy
Atas dasar lisensi dari : -
Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 12 Juli 2028.
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.



Manufactured by:
EUROCOLUMBUS S.R.L.
Via Firlago 36, 20143 Milano, Italy



alienX

Distributed by:
PT. Rajawali Medika Mandiri
Jl. Rajawali Sakti
Komp. Rajawali Sakti Permai B.22-23,
Bandung 40183 INDONESIA
KEMENKES RI AKL:





MONITOR 31" BARCO



Generator from 12 to 25KW



RDW systems to reduce the dose



X ray tube up to 400 KHU



EPD anticollision side FPD and RX



WAD + EHC to guarantee endless fluoroscopy



New trolley with ETS15 synchronized with ETS15 on C arm



Preview of the images on ETS15



Flat panel 2020-2121-3030 and SO LINUX



Movement of C arm motorized & manual



DSA (optional)







eurocolumbus s.r.l.
Via Filargo, 36 - 20143 Milano - Italia
apparecchiature radiologiche elettromedicali



n. 0051

modello
model

alien X

REF

X|XX|XX|X|X|X|X|X|X|X|X

matricola
serial

anno
year

Rev. 01.2019-01

alimentazione
power supply

220 - 240V - 50/60Hz - XXA


Classe I
Tipo B

nota: l'indicazione dei parametri radiologici e di filtrazione totale è riportata
sul frontale della cuffia radiogena

*note: the indication of the radiologic parameters and total filtration are reported
on the frontside of the tube head*



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Komp. Rajawali Sakti Permai B.22-23,

Bandung 40183 INDONESIA

KEMENKES RI AKL:



TECHNICAL CHARACTERISTICS ALIEN X

Dimensions	Stand: Width: 800 mm Lenght: 1960 -2100 mm depending on the version Height: 1710 - 1840 mm depending on the version Trolley: Width: 550 mm Lenght: 550 mm Height: 1600 -1900 mm
Weight	Stand (without monitor trolley): from 360 Kg to 400 Kg depending on the version Trolley: from 135 Kg to 165 Kg (depending on the configuration)
C-Arm geomertry	Free space within tubehead and detector: without DFF/SID 850 mm. With DFF/SID 850-730 mm /920-800 mm depending on the version C-arm depth: 690/730/750 mm depending on configurations
Movement range	Horizontal excursion: 200/250/280 mm depending on configuration Orbital: +/- 210°, +/- 225° depending on the version Rotational: 180°, 150°, 140° depending on the version Lift: 500 mm DFF/SID: 1050 for alien e version alien (2020/2121/3030) and alien X Variable DFF/SID: 1050/930 for alien e version alien (2020/2121/3030) cardio; 1120 -1108 for alien e version alien (202075/212175/303075) Wig-wag (horizontal oscillation): +/- 8° or +/- 12° depending on configuration
Supply	220-240 Vac - 50/60 Hz Nominal power: 2990VA - 3680VA - 5750 VA depending on configurations Working current: 13/16/25 A depending on configurations Requires following socket and protections With BOOSTER (25kW) • IEC309 single phase interlocked socket, 16 A, P+N+PE • Circuit braker: 13A curve C or 16A curve C depending on configuration • Supply resistance < 0.75 ohm Without BOOSTER: • IEC309 single phase interlocked socket, 32 A, P+N+PE • Circuit brakernot less than 25A curve C • Supply resistance < 0.50 ohm

Environmental conditions	Ambient temperature:	During use	+10 / +35°C
		Stocking / transport	-25 / +70°C
	Umidity:	During use	20 / 80% Ur not condensing
		Stocking / transport	5 / 95% Ur not condensing
	Atmosferic pressure:	During use	700 a 1020 hPa
		Stocking / transport	500 a 1060 hPa (375 - 795 mm Hg)



1. GENERATOR CHARACTERISTICS

Inverter frequency	40 KHz
Output nominal power depending on versions	12 KW - 100 kV - 120 mA - 0.1 sec 15 KW - 90 kV - 160 mA - 0.1 sec 25 KW - 100 kV - 250 mA - 0.1 sec
Max output tube current	From 120mA to 250mA depending on configurations
Max tube voltage	125 KV
Scopy Cont subordinated to the will of the operator	Yes
Scopy	Yes
Scopy: current settable at the maximum voltage	Version 12kW: 90 mA a 125kV Version 15kW: 120 mA a 125kV Version 25kW: 150 mA a 125kV
Scopy: voltage settable at the maximum current	Version 12kW: 100 kV a 120mA Version 15kW: 60 kV a 250mA Version 25kW: 65 kV a 250mA
Scopy HQ: current settable at the maximum voltage	Version 12kW: 90 mA a 125kV Version 15kW: 120 mA a 125kV Version 25kW: 150 mA a 125kV
Scopy HQ: voltage settable at the maximum current	Version 12kW: 100 kV a 120mA Version 15kW: 60 kV a 250mA Version 25kW: 65 kV a 250mA
Scopy - mA max	12kW a 120mA 15kW a 250mA 25KW a 250mA
Scopy - KV range	from 40 kV to 125 kV
Scopy HQ - mA max	12kW at 120mA 15kW at 250mA 25KW at 250mA
Scopy HQ - KV range	from 40 to 125 kV
Graphy DR - mA max	12kW at 120mA 15kW at 250mA 25KW at 250mA
Graphy DR- kV range	from 40 to 125 kV
Pulsed exposure framerates	Up to 30 frame/sec

2. TUBE, FLAT PANEL E MONITOR AVAILABLE

TUBE	RTM 80HS - 400KHU on housing C33 - 1.200 W dissipation	Focal Spots - mm 0.3 x 0.5 low - high speed
	G689 - 600KHU on housing B146H - 1.200 W dissipation	Focal Spots - mm 0.3 x 0.6 low - high speed
	G896 - 857KHU on housing B146H - 1.200 W dissipation	Focal Spots - mm 0.6 x 1.0 low - high speed
	RTM 70HS - 300KHU on housing C30 - C32 600 - 1.000 W dissipation	Focal Spots - mm 0.3x0.6 low - high speed
	RAD 99B - 300KHU on housing B145W 600 W dissipation	Focal Spots - mm 0.3 x 0.6 low speed

FLAT PANEL	PS 2020	1024x1024x16bit
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	PS 2121	1024x1024x16bit
	PS 3030	1536x1536x16bit
	VW1212ga	2048x2048x16bit
MONITOR	MVCD1619	1280x1024
	MVGD1619	1280x1024
	MVCD-4127 HBT	2560x1440
	MDAC 8331 HPEW	3860x2160 – 4096x2160

3. X-RAY TUBE ASSEMBLY CHARACTERISTICS

C33-RTM80HS CHARACTERISTICS

Tube	Focal spots	03/05 mm	
	Rotating anode speed	3000 rpm	9000 rpm
	Nominal anode power	Small focal spot 6kW Large focal spot 25kW	Small focal spot 10kW Large focal spot 45kW
	Anode angle	10°	
	Anode heat storage capacity	300 KJ (400 kHU)	
	Maximum anode dissipation	1300 W (104 kHU/min)	
Tube assembly	Heat Storage Capacity with WAD	7.000.000HU o 8.000.000HU	
	Maximum continuous heat dissipation	1200 W	
	Min. tube assembly inherent filtration	1.2 mm Al	
	Total filtration	>5 mm Al	



eurocolumbus s.r.l. Via Filargo, 36 - 20143 Milano - Italia apparecchiature radiologiche elettromedicali		CE	n. 0051
modello model	alien X		
REF	X XX XX X X X X X X X		
matricola serial		anno year	
alimentazione power supply		220 - 240V - 50/60Hz - XXA	
nota: l'indicazione dei parametri radiologici e di filtrazione totale è riportata sul frontale della cuffia radiogene note: the indication of the radiologic parameters and total filtration are reported on the frontside of the tube head		Classe I Tipo B	



The identification plate shown here is to be considered an example. The model of the equipment to which this manual was attached may be different.

SAFETY SYMBOLS AND LABELING



Attention, refer to the user manual. Safety information



Insulation class I and applied part of type B



Do not dispose of this product and its accessories as general waste. Prepare the product for recycling or recycling as indicated by the Legislative Decree of March 14, 2014, n. 49 "Implementation of Directive 2012/19 / EU on waste electrical and electronic equipment (WEEE)".



Complies with Council Directive 93/42 / EEC and s.m.i., DM Class IIb.
The 4-digit code indicates the certifying body of the device.



SWITCH OFF

Before any intervention on parts marked with this label, it is mandatory to switch off the power supply to the machine.



ATTENTION TO HANDS

This symbol calls attention to a possible source of danger specifically to the position of the hands.



ELECTRICAL SHOCK DANGER

This symbol calls attention to a possible one danger of electric shock. Care should be taken to access and operate on parts and areas indicated by this symbol.



LASER emission

This symbol identifies a laser light emission element. These elements can be a source of danger for vision. Do not look at the emitter directly.

