Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Vipromed Service SRL, cu sediul str. Valea Trandafirilor 20,
(adresa)

Mun. Chisinau, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

RAYBOW FLEX DR
RAYBOW XE
CYBERBLOC FP S

Sunt autentice și corespund realității.

Digitally signed by Savca Octavian
Date: 2023.11.24 12:50:52 EET
Reason: MoldSign Signature
Location: Moldova

Numele, prenumele şi funcţia *Semnătura* _____

***Octavian SAVCA**, Administrator* *Data* _____

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ..... din .....

Solicitantul Vipromed Service SRL, cu sediul str. Valea Trandafirilor 20
(adresa)
Mun. Chisinau, tel./fax: 069567188, e-mail vipromed@gmail.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

RAYBOW FLEX DR
RAYBOW XE
CYBERBLOC FP S

Se anexează următoarele acte:
CE Certificate (Ningbo Runyes Medical Instrument Co,. Ltd)
EC Declaration of Conformity
Declaratie pe propria raspundere
Letter of Authorization

Data _____ Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Instalatie radiologica	PRIMAX INTERNATIONAL srl	RAYBOW FLEX DR	
		Instalatie radiologica	PRIMAX INTERNATIONAL srl	RAYBOW XE	
		Instalatie radiologica	PRIMAX INTERNATIONAL srl	CYBERBLOC FP S	

RADIOLOGIA SA

Algete, June 1st, 2023

Ref: ES19/85995.01 extension

Extension validity certificate CE RADIOLOGÍA, S.A. to 2028/12/31

To whom it may concern

In accordance with the transitional provisions of Regulation EU 2023/607 amending the regulation of medical devices (EU) 2017/745 and the regulation of in vitro diagnostic medical devices (EU) 2017/746, the notified body SGS Belgium NV confirms the extension of validity of the CE certificate of RADIOLOGÍA, S.A with reference ES19/85995.00 Issue 6 until 31st December 2028, as they are non-implantable class IIb and comply with the terms of the transitory provisions.

Attached is the CE certificate of RADIOLOGÍA, with reference ES19/85995.01 Issue 3, and the letter from the Notified Body SGS Belgium NV, with reference CLNB1639 - ES/MAD/300003519, confirming the extension of the certificate.

Sincerely

RADIOLOGIA, S.A.
N.I.F.: A28047991
C. Pelaya, 13. Pol. Ind. Río de Janeiro
28110 ALGETE (Madrid)
España

Juan Antonio Sánchez Argüelles
Person Responsible for Regulatory Compliance

Radiología S.A.
Polígono Industrial Rio de Janeiro
C/ Pelaya, 9-13
28110 Algete, Madrid. Spain

20th April 2023

Confirmation Letter Reference: CLNB1639 - ES/MAD/300003519

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Radiología S.A.
Polígono Industrial Rio de Janeiro
C/ Pelaya, 9-13
28110 Algete, Madrid. Spain

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry.
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices

- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

pp
[Sean Kelly]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
X-Ray Generator RST: RST-1010, RST-1015, RST-1020, RST-1025, RST-1030, RST-1035, RST-1610, RST-1615, RST-1620, RST-1625. RST-1630. RST-1635, RST-210, RST-215, RST-220, RST-225, RST-230, RST-235, RST-310, RST-315, RST-320, RST-325, RST- 330, RST-335, RST-410, RST-415, RST-420, RST-425, RST-430, RST- 435,	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
RST-510, RST-515, RST-520, RST-525, RST-530, RST-535, RST- 610, RST-615, RST-620, RST-625, RST-630, RST-635, RST-835 RST- 1610 PSU, RST-1615 PSU, RST-210 PSU, RST-215 PSU, RST-310 PSU, RST-315 PSU, RST-410 PSU, RST- 415 PSU, RST-510 PSU, RST-515 PSU RST-1610-C, RST-1615-C, RST- 210-C, RST-215-C, RST-310-C, RST-315-C, RST-410-C, RST-415-C, RST-510-C, RST-515-C			
X-Ray Generator RSTR: RSTR100, RSTR200, RSTR300, RSTR400, RSTR500, RSTR600, RSTR800	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
Battery Mobile X-Ray Unit PIONEER: PIONEER	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
Battery Mobile X-ray Unit TRANSPORTIX B: TX-20HF-Batt, TX- 32HF-Batt, TX-40HF-Batt, TX-50HF- Batt TX-20HF-B-D-C, TX-32HF-B-D-C,TX-40HF-B-D-C, TX-50HF-B-D-C TX-20HF-B-D-TEZ, TX-32HF-B-D-TEZ, TX-40HF-BTEZ, TX-50HF-B-D-TEZ	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TX-20HF-B-D-FDX, TX-32HF-B-D-FDX, TX-40HF-B-D-FDX, TX-50HF-B- D-FDX TX-20HF-B-D-FDXW, TX- 32HF-B-D-FDXW, TX-40HF-B-D- FDXW, TX-50HF-B-D-FDXW			
Capacitor Mobile X-ray Unit TRANSPORTIX MLP: TX-16-MLP, TX-20-MLP, TX-32-MLP	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
Portable X-ray Unit TRANSPORTIX L: TXL-2.0, TXL-4.0, TXL-8.0, TXL- PLUS4, TXL-PLUS8, TXL-PLUS4- APR, TXL-PLUS8-APR, TXLW4, TXLW8, TXL4HC, TXL8HC	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
Radiographic System UNIVERSAL X: UNIVERSAL X BRS Composed of: Radiographic Positioner: UNIVERSAL X BRS UNIVERSAL X URS Composed of: Radiographic Positioner: UNIVERSAL X URS Control Box: UNIVERSAL X URS UNIVERSAL X PLUS ADVANCED Composed of: Radiographic Positioner: UNIVERSAL X PLUS ADVANCED Control Box: UNIVERSAL X PLUS ADVANCED	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Radiographic System POLYRAD PREMIUM: POLYRAD PREMIUM Composed of: Tube stand POLYRAD PREMIUM: POLYPRE-FMTS Tube stand POLYRAD PREMIUM: POLYPRE-FMTS-TS Tube stand ADV POLYRAD PREMIUM: POLYPRE-FMTSSADV Fixed height Table POLYRAD PREMIUM: POLYPRE-FWFTT-B Elevating Table POLYRAD PREMIUM: POLYPRE-EL-B Wall Stand, POLYRAD PREMIUM: POLYPRE-WBS Wall Stand POLYRAD PREMIUM: POLYPRE-WBS-TS Tomography POLYRAD PREMIUM: POLYPRE-TOMO Power Supply: BRAKE BOX R POLYRAD PREMIUM ADVANCED AT Composed of: Tube stand POLYRAD PREMIUM ADVANCED AT: POLYPRE-FMTSAT-ADV Elevating Table POLYRAD PREMIUM ADVANCED AT: POLYPRE-ELAT-ADV Wall Stand POLYRAD PREMIUM ADVANCED AT: POLYPRE-WBSAT-ADV Wall Stand Manual Tilting: TRWBS-TILT	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Tomography POLYRAD PREMIUM ADVANCED: POLYPRE-TOMO-ADV POLYRAD PREMIUM ADVANCED Composed of: Tube stand POLYRAD PREMIUM ADVANCED: POLYPRE-FMTSTPC-ADV Elevating Table POLYRAD PREMIUM ADVANCED: POLYPRE-ELTPC-ADV Wall Stand POLYRAD PREMIUM ADVANCED: POLYPRE-WBSTPC-ADV Wall Stand Manual Tilting: TRWBS-TILT Tomography POLYRAD PREMIUM ADVANCED: POLYPRE-TOMO-ADV			
Radiographic System POLYRAD: POLYRAD S Composed of: Tube stand POLYRAD S: POLY-S-FMTS Table POLYRAD S: POLY-FWFTT Wall Stand POLYRAD S: POLY-S-WBS Power Supply: BRAKE BOX R POLYRAD SE Composed of: Tube stand POLYRAD S: POLY-S-FMTS Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET Wall Stand POLYRAD S: POLY-S-WBS	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Wall Stand POLYRAD PREMIUM:POLYPRE –WBS Power Supply: BRAKE BOX R			
Radiographic System POLYRAD PREMIUM CS: POLYRAD PREMIUM CSAP Composed of: Ceiling Suspension POLYRAD PREMIUM CS: CSAP Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET-AP Moving Elevating Table: POLYFLEX Wall Stand POLYRAD PREMIUM NBS: NBSTILTMAP POLYRAD PREMIUM CSAT Composed of: Ceiling Suspension POLYRAD PREMIUM CS: CSAT Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET-AT Moving Elevating Table: POLYFLEX Wall Stand POLYRAD PREMIUM NBS: NBSTILTMAT Wall Stand Manual Tilting: TRWBS-TILT POLYRAD PREMIUM CSST Composed of: Ceiling Suspension POLYRAD PREMIUM CS: CSST Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Moving Elevating Table: POLYFLEX Wall Stand POLYRAD PREMIUM NBS: NBSTILTM Wall Stand Manual Tilting: TRWBS-TILT			
Radiographic System POLYRAD PREMIUM CSX: POLYRAD PREMIUM CSX AP Composed of: Ceiling Suspension POLYRAD PREMIUM CSX: CSXAP Elevating Table POLYRAD PREMIUM NET400: NET400AP Elevating Table POLYRAD PREMIUM NET500: NET500AP Wall Stand POLYRAD PREMIUM CSXWS: CSXWSAP X-Ray Generator Console: STH	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
X-Ray Generator Console: CTSC	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
Remote-controlled Table X-Ray System XCELLENCE: XCELLENCE DYNAMIC	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
Mammographic System FEMINA: FEMINA FEMINA DIGITAL	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.01; NB1639
Battery Mobile X-Ray Unit RAYBOW XE: RAYBOW XE	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Battery Mobile X-ray Unit RAYBOW B: PM-20HF-Batt, PM-32HF-Batt, PM- 40HF-Batt, PM-50HF-Bat	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Battery Mobile X-ray Unit RAYBOW DR-C: PM-20HF-B-D-C, PM-32HF-B-D-C PM-40HF-B-D-C, PM-50HF-B-D-C	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Battery Mobile X-ray Unit RAYBOW DR-T: PM-20HF-B-D-TEZ, PM-32HF-B-D-TEZ, PM-40HF-B-D-TEZ, PM- 50HF-B-D-TEZ	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Battery Mobile X-ray Unit RAYBOW DR-F: PM-20HF-B-D-FDX, PM-32HF-B-D-FDX, PM-40HF-B-D-FDX, PM-50HF-B-D-FDX PM-20HF-B-D-FDXW, PM-32HF-B-D-FDXW, PM-40HF-B-D- FDXW, PM-50HF-B-D-FDXW	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Capacitor Mobile X-ray Unit RAYBOW C: PM-16-MLP, PM-20- MLP, PM-32-MLP	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Portable X-ray Unit RAYBOW FLEX: PPL-4.0, PPL-8.0, PML4, PML8, PML4-APR, PML8-APR, PMLW4, PMLW8, PML4HC, PML8HC	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Radiographic System RIVIERA: RIVIERA BRS Composed of:	Class IIb	N/A	Certificate ES19/85995.00,

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Radiographic Positioner: RIVIERA X BRS RIVIERA URS Radiographic Positioner: RIVIERA X URS Control Box: RIVIERA X URS RIVIERA LP PLUS Radiographic Positioner: RIVIERA X PLUS ADVANCED Control Box: RIVIERA X PLUS ADVANCED			ES19/85995.02; NB1639
Radiographic System RIVIERA B: RIVIERA B Composed of: Tube stand POLYRAD PREMIUM: RIVB-FMTS Tube stand ADV POLYRAD PREMIUM: RIVB-FMTSSADV Fixed height Table POLYRAD PREMIUM: RIVB-FWFTT-B Elevating Table POLYRAD PREMIUM: RIVB-EL-B Wall Stand POLYRAD PREMIUM: RIVB-WBS Tomography POLYRAD PREMIUM: RIVB-TOMO Power Supply: BRAKE BOX R RIVIERA B AT Composed of: Tube stand POLYRAD PREMIUM ADVANCED AT: RIVB-FMTSAT-ADV Elevating Table POLYRAD PREMIUM ADVANCED AT: RIVB-ELAT-ADV	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Wall Stand POLYRAD PREMIUM ADVANCED AT: RIVB-WBSAT-ADV Wall Bucky Stand Manual Tilting: TRWBS-TILT Tomography POLYRAD PREMIUM ADVANCED: RIVB-TOMO-ADV RIVIERA B TPC Composed of: Tube stand POLYRAD PREMIUM ADVANCED: RIVB-FMTSTPC-ADV Elevating Table POLYRAD PREMIUM ADVANCED: RIVB-ELTTPC-ADV Wall Stand POLYRAD PREMIUM ADVANCED: RIVB-WBSTPC-ADV Wall Stand Manual Tilting: TRWBS- TILT Tomography POLYRAD PREMIUM ADVANCED: RIVB-TOMO- ADV			
Radiographic System RIVIERA SP: RIVIERA SP Composed of: Tube stand POLYRAD S: RIVSP-FMTS Table POLYRAD S: RIVSP-FWFTT Wall Stand POLYRAD S: RIVSP-WBS Power Supply: BRAKE BOX R RIVIERA SPV Composed of: Tube stand POLYRAD S: RIVSP-FMTS Elevating Table POLYRAD PREMIUM NET: RIVSPV Wall Stand POLYRAD S: RIVSP-WBS	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Wall Stand POLYRAD PREMIUM: RIVB-WBS Power Supply: BRAKE BOX R			
Radiographic System RIVIERA CS: RIVIERA CSAP Composed of: Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSAP Elevating Table POLYRAD PREMIUM NET: RIVSPV-AP Moving Elevating Table: RIV-FLEX Wall Stand POLYRAD PREMIUM NBS: RIVC- NBSTILTMAP RIVIERA CSAT Composed of: Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSAT Elevating Table POLYRAD PREMIUM NET: RIVSPV-AT Moving Elevating Table: RIV-FLEX Wall Stand POLYRAD PREMIUM NBS: RIVC-NBSTILTMAT Wall Stand Manual Tilting: TRWBS-TILT RIVIERA CSST Composed of: Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSST Elevating Table POLYRAD PREMIUM NET: RIVSPV Moving Elevating Table: RIV-FLEX Wall Stand POLYRAD PREMIUM NBS: RIV-NBSTILTM Wall Stand Manual Tilting: TRWBS-TILT			Certificate ES19/85995.00, ES19/85995.02; NB1639

Device name	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Radiographic System RIVIERA CSX: POLYRAD PREMIUM CSX AP Composed of: Ceiling Suspension POLYRAD PREMIUM CSX: RIV-CSXAP Elevating Table POLYRAD PREMIUM NET400: RIVSPV400AP Elevating Table POLYRAD PREMIUM NET500: RIVSPV500AP Wall Stand POLYRAD PREMIUM CSXWS: CSXWSAP X-Ray Generator Console: STH	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
X-Ray Generator CONSOLE: CTSC	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Remote Control Table X-Ray System: LEVIA	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
Mammographic System DULCIA: DULCIA DULCIA DIGITAL	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639
X-Ray Generator RSTR: PM-RSTR300, PM-RSTR400, PM-RSTR500, PM-RSTR600, PM-RSTR800	Class IIb	N/A	Certificate ES19/85995.00, ES19/85995.02; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action

2023/04/20	Version 1	Initial issue

CERTIFICATO CE

Certificato n. 1074/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI SRL

24060 TORRE DE' ROVERI (BG) - VIA A.VOLTA 10 (ITA) - Italy

mantiene nello stabilimento di:

24060 TORRE DE' ROVERI (BG) - VIA A.VOLTA 10 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Unità mobile con arco a C per fluoroscopia e radiografia

Sistemi di acquisizione ed elaborazione immagini radiologiche

Modd. come da documento 'Allegato al Certificato CE no. 1074/MDD - Elenco dei Dispositivi' rev. 0 del 2021/03/03; tale allegato costituisce parte integrante e sostanziale del presente certificato.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

10AH00214; 10AI00073, 10AJ00199, 10EK00020; 10AK00254; 10AL00039; COMEDCONMHDM110048027-01; COMEDCONMHDM120070098-01; 10AM00103; 10AN00054; 10AN00078; 10AO00078; DM14A0357386-01; DM15A0505039-01; DM16E0629133-01; DM16-0000855; DM17-0019515; DM18-0022370-01; DM19-0036399-01; DM19-0040806-01; DM19-0034532-01; DM19-0046216-01; DM20-0048200-01; DM19-0034862-01; DM19-0037923-01; DM20-0056284-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2007-10-30
Data aggiornamento:	2021-03-03
Sostituisce:	2020-03-18
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1074/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI SRL

24060 TORRE DE' ROVERI (BG) - VIA A.VOLTA 10 (ITA) - Italy

manages in the factory of:

24060 TORRE DE' ROVERI (BG) - VIA A.VOLTA 10 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Mobile C-arm unit for fluoroscopy and radiography

X-ray Image acquisition and processing systems

Type ref. as to document 'Annex of EC Certificate no. 1074/MDD - Device List' rev. 0 dated 2021/03/03; this annex is integral and substantial part of this certificate.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AH00214; 10AI00073, 10AJ00199, 10EK00020; 10AK00254; 10AL00039; COMEDCONMHDM110048027-01; COMEDCONMHDM120070098-01; 10AM00103; 10AN00054; 10AN00078; 10AO00078; DM14A0357386-01; DM15A0505039-01; DM16E0629133-01; DM16-0000855; DM17-0019515; DM18-0022370-01; DM19-0036399-01; DM19-0040806-01; DM19-0034532-01; DM19-0046216-01; DM20-0048200-01; DM19-0034862-01; DM19-0037923-01; DM20-0056284-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2007-10-30
Updated:	2021-03-03
Substitution Date:	2020-03-18
Expiry Date:	2024-05-26

IMQ

Allegato al Certificato CE n. 1074/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1074/MDD - Device List

rev. 0 del/of **2021/03/03**

Marca/Marche: Trade mark(s):	**PRIMAX International**

Categoria di dispositivo: Device category:	**Unità mobile con arco a C per fluoroscopia e radiografia** Mobile C-arm unit for fluoroscopy and radiography
Modello/i: Model(s):	**Cyberbloc FP-S**
Modello/i: Model(s):	**Cyberbloc FP** Ref. • Rk0521S; • Rk0530S; • Rk2021S; • Rk2030S

Categoria di dispositivo: Device category:	**Sistemi di acquisizione ed elaborazione immagini radiologiche** X-ray acquisition and processing systems
Modello/i: Model(s):	**HIRIS RF43;** **HIRIS RF43-FL;** **HIRIS RF43-TS**
Modello/i: Model(s):	**PRIMO;** **PRIMO R;** **primo-W**

A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI S.R.L

DICHIARAZIONE DI CONFORMITÀ

DECLARATION OF CONFORMITY

Nome del costruttore *Manufacturer's name*	A.T.S. applicazione tecnologie speciali s.r.l. via A. Volta 10 – 24060 Torre de' Roveri (BG) - Italy
Prodotto *Product*	unità mobile con arco a C per fluoroscopia e radiografia *mobile C-arm unit for fluoroscopy and radiography*
Modello *Type ref.*	**Cyberbloc FP-S** Ref. • SF21; • SR21; • SR30.
Marca *Trade mark*	PRIMAX INTERNATIONAL
Conformità *Conformity*	Direttiva Dispositivi Medici 93/42/CEE e s.m.i. *Medical devices directive 93/42/EEC and its revised version*
Norme applicate *Applied standards*	EN ISO 13485, EN ISO 14971, EN 60601-1, EN 60601-1-2, EN 60601-1-3, EN 60601-1-6, EN 62366-1, EN 60601-2-28, EN 60601-2-43, EN 60601-2-54, EN 62304, EN 60825-1, EN 15223-1, EN 1041, DICOM 3.0 Edizione in vigore alla data di emissione del documento *Current edition at document issue date*
Classificazione *Classification*	Classe IIb (Allegato IX della Direttiva 93/42/CEE, regola 10) *Class IIb (Annex IX Directive 93/42/EEC, rule 10)*

In rappresentanza del costruttore, con la presente dichiaro che il prodotto sopraindicato è conforme ai requisiti essenziali dell'allegato I della Direttiva 93/42/CEE e s.m.i.
As the appointed representative of the manufacturer, I hereby declare that the product specified above conforms to the essential requirements listed in annex I of Directive 93/42/EEC and its revised version.

Questa dichiarazione è supportata dal certificato CE di "**Dichiarazione di approvazione del sistema qualità**" n° **1074/MDD** emesso da **IMQ**, Organismo Notificato n° 0051, secondo quanto previsto dall'allegato II, con l'esclusione del punto 4, della Direttiva 93/42/CEE e s.m.i.
This declaration is supported by EC "Quality System Approval" certificate number 1074/MDD issued by IMQ, Notified Body no. 0051, covering the provisions annex II, excluding section 4, of Directive 93/42/EEC and its revised version.

Torre de' Roveri: 19-10-2023

Regulatory Affairs Manager: Livia Pillitteri

ATS Applicazione Tecnologie Speciali S.r.l.
Via A. Volta, 10 - ph. +39.035.584311
24060 TORRE DE' ROVERI (Bergamo) - ITALY
CF/PI 02037400161 - a Socio Unico

PIONEERS SINCE 1942

RADIOLOGIA SA

DECLARACIÓN CE DE CONFORMIDAD CON EL MARCADO CE

(DIRECTIVA DE PRODUCTOS SANITARIOS 93/42/CEE MODIFICADA POR 2007/47/CE-REAL DECRETO 1591/2009)

EC DECLARATION OF CONFORMITY FOR EC MARKING

(FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC-SPANISH ROYAL DECREE 1591/2009)

Nosotros
We

RADIOLOGÍA, S.A.
C/Pelaya 13, Polígono Industrial Río de Janeiro, 28110 Algete (Madrid), España

Declaramos bajo nuestra responsabilidad que los productos son clasificados Clase IIb aplicando la Regla 10 del Anexo IX de la Directiva:
Declare under our sole responsibility that the Products are classified Class IIb applying Rule 10 of Annex IX of the Directive:

Equipo Móvil de Rayos-X de Baterías RAYBOW XE: *(Battery Mobile X-Ray Unit RAYBOW XE):*

RAYBOW XE

Equipo Móvil de Rayos-X de Baterías RAYBOW B: *(Battery Mobile X-Ray Unit RAYBOW B):*

PM-20HF-Batt, PM-32HF-Batt, PM-40HF-Batt, PM-50-HF-Batt.

Equipo Móvil de Rayos-X de Baterías RAYBOW DR-C: *(Battery Mobile X-Ray Unit RAYBOW DR-C):*

PM-20HF-B-D-C, PM-32HF-B-D-C, PM-40HF-B-D-C, PM-50HF-B-D-C

Equipo Móvil de Rayos-X de Baterías RAYBOW DR-T: *(Battery Mobile X-Ray Unit RAYBOW DR-T):*

PM-20HF-B-D-TEZ, PM-32HF-B-D-TEZ, PM-40HF-B-D-TEZ, PM-50HF-B-D-TEZ

Equipo Móvil de Rayos-X de Baterías RAYBOW DR-F: *(Battery Mobile X-Ray Unit RAYBOW DR-F):*

PM-20HF-B-D-FDX, PM-32HF-B-D-FDX, PM-40HF-B-D-FDX, PM-50HF-B-D-FDX,
PM-20HF-B-D-FDXW, PM-32HF-B-D-FDXW, PM-40HF-B-D-FDXW, PM-50HF-B-D-FDXW

Marca: PRIMAX INTERNATIONAL
Trade mark

están en conformidad con los Requisitos Esenciales que le son aplicables (Anexo I).
are in compliance with the Essential Requirements which apply to them (Annex I)

Esta conformidad está basada en los siguientes elementos:
This compliance is based on the following elements:

- La información contenida en el **"Archivos Técnicos TF-041 y TF-090"** de los productos al que esta declaración hace referencia.
  *Information included in the **"Technical Files TF-041&TF-090"** of the Product to which this declaration relates.*

- Certificado CE de aprobación del Sistema completo de Aseguramiento de la Calidad (Anexo II excluyendo la Sección 4) emitido por el **Organismo Notificado Nº 1639,** SGS Belgium NV, Certificado No. ES19/85995.02
  *CE certificate: approval of full Quality Assurance System (Annex II excluding Section 4) delivered by the **Notified Body No. 1639,** SGS Belgium NV, Certificate No. ES19/85995.02*

SGS SGS SGS SGS

+34 902 19 57 70 PHONE	+34 902 10 33 67 FAX	radiologia@radiologia-sa.com EMAIL	www.radiologia-sa.com WEB
C/ Pelaya, 13, Pol. Ind. Río de Janeiro - 28110 Algete, Madrid (Spain) ADDRESS			

PIONEERS SINCE 1942

RADIOLOGIA SA

RADIOLOGIA, S.A.
N.I.F.: A28047991
C/ Pelayo, 13 Pol. Ind. Río de Janeiro
28110 ALGETE (Madrid)
España

Fecha (*Date*): 23 / 09 / 2020

Maria Luisa Gómez de Agüero Gómez
Directora de Calidad y Reglamentación
Quality & Regulatory Director

PIONEERS SINCE 1942

RADIOLOGIA SA

DECLARACIÓN CE DE CONFORMIDAD CON EL MARCADO CE

(DIRECTIVA DE PRODUCTOS SANITARIOS 93/42/CEE MODIFICADA POR 2007/47/CE-REAL DECRETO 1591/2009)

EC DECLARATION OF CONFORMITY FOR EC MARKING

(FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC-SPANISH ROYAL DECREE 1591/2009)

Nosotros
We

RADIOLOGÍA, S.A.
C/Pelaya 13, Polígono Industrial Río de Janeiro, 28110 Algete (Madrid), España

Declaramos bajo nuestra responsabilidad que los productos son clasificados Clase IIb aplicando la Regla 10 del Anexo IX de la Directiva:
Declare under our sole responsibility that the Products are classified Class IIb applying Rule 10 of Annex IX of the Directive:

- **Unidad Portátil de Rayos X RAYBOW FLEX** *(Portable X-Ray Unit RAYBOW FLEX)*:

PPL-4.0, PPL-8.0
PML4, PML8
PML4-APR, PML8-APR
PMLW4, PMLW8
PML4HC, PML8HC

están en conformidad con los Requisitos Esenciales que le son aplicables (Anexo I).
are in compliance with the Essential Requirements which apply to them (Annex I)

Esta conformidad está basada en los siguientes elementos:
This compliance is based on the following elements:

- La información contenida en el **"Archivos Técnicos TF-064, TF-089"** de los productos al que esta declaración hace referencia.
  *Information included in the **"Technical Files TF-064, TF-089"** of the Product to which this declaration relates.*

- Certificado CE de aprobación del Sistema completo de Aseguramiento de la Calidad (Anexo II excluyendo la Sección 4) emitido por el **Organismo Notificado Nº 1639,** SGS Belgium NV, Certificado No. ES19/85995.02
  *CE certificate: approval of full Quality Assurance System (Annex II excluding Section 4) delivered by the **Notified Body No. 1639,** SGS Belgium NV, Certificate No. ES19/85995.02*

RADIOLOGIA, S.A.
N.I.F.: A28047991
C/ Pelayo, 13-Pol. Ind. Río de Janeiro
28110 ALGETE (Madrid)
España

Fecha (*Date*): 9 / 09 / 2020

María Luisa Gómez de Agüero Gómez
Directora de Calidad y Reglamentación
Quality & Regulatory Director

PIONEERS SINCE 1942

RADIOLOGIA SA

DECLARACIÓN CE DE CONFORMIDAD CON EL MARCADO CE

(DIRECTIVA DE PRODUCTOS SANITARIOS 93/42/CEE MODIFICADA POR 2007/47/CE-REAL DECRETO 1591/2009)

EC DECLARATION OF CONFORMITY FOR EC MARKING

(FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC-SPANISH ROYAL DECREE 1591/2009)

Nosotros
We

RADIOLOGÍA, S.A.
C/Pelaya 13, Polígono Industrial Río de Janeiro, 28110 Algete (Madrid), España

Declaramos bajo nuestra responsabilidad que los productos son clasificados Clase IIb aplicando la Regla 10 del Anexo IX de la Directiva:
Declare under our sole responsibility that the Products are classified Class IIb applying Rule 10 of Annex IX of the Directive:

- **Unidad Móvil de Baterías RAYBOW XE** *(Battery Mobile X-Ray Unit RAYBOW XE)*:

RAYBOW XE

están en conformidad con los Requisitos Esenciales que le son aplicables (Anexo I).
are in compliance with the Essential Requirements which apply to them (Annex I)

Esta conformidad está basada en los siguientes elementos:
This compliance is based on the following elements:

- La información contenida en el **"Archivo Técnico TF-090"** de los productos al que esta declaración hace referencia.
  *Information included in the **"Technical File TF-090"** of the Product to which this declaration relates.*

- Certificado CE de aprobación del Sistema completo de Aseguramiento de la Calidad (Anexo II excluyendo la Sección 4) emitido por el **Organismo Notificado Nº 1639,** SGS Belgium NV, Certificado No. ES19/85995.02
  *CE certificate: approval of full Quality Assurance System (Annex II excluding Section 4) delivered by the **Notified Body No. 1639,** SGS Belgium NV, Certificate No. ES19/85995.02*

RADIOLOGIA, S.A.
N.I.F.: A28047991
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28110 ALGETE (Madrid)
España

Fecha (*Date*): 9 / 09 / 2020

Maria Luisa Gómez de Agüero Gómez
Directora de Calidad y Reglamentación
Quality & Regulatory Director

Torre de' Roveri, 10.11.2023

Letter of Authorization for Authorized Representatives

Dear Sir/Madam,

Subject: **Letter of Authorization for SRL VIPROMED SERVICE**

We, **PRIMAX INTERNATIONAL Srl** as the Product Owner, hereby authorize SRL VIPROMED SERVICE as our products authorized distributor in the territory of Republic of Moldova.

We authorize SRL VIPROMED SERVICE to:

- Arrange importation and registration of our products according to legal requirements of regulatory bodies and appropriate government institutions in the territory of Republic of Moldova to ensure maximum success of the marketing of our products.
- Use for marketing purposes the trade name, technical specifications, description, and pictures of our products.
- Participate in various tenders.
- Provide the servicing and repairing to our equipment.

This authorization shall apply to the following medical devices:

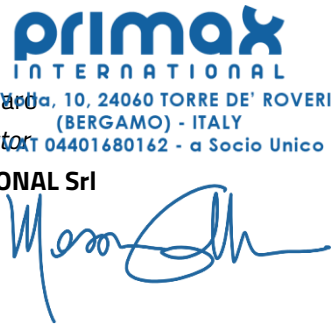
1. Cyberbloc FP-S
2. Raybow XE
3. Raybow Flex DR

Via A. Volta, 10 24060 Torre De' Roveri BG Italy
+39.035.4500002 e-mail:sales@primaxint.com
primaxint.com
PI/VAT 04401680162 – a Socio Unico

This authorization shall remain until the 31st of December 2024.

Yours Sincerely,

Massimo Cavallaro
Managing Director
PRIMAX INTERNATIONAL Srl



Via A. Volta, 10 24060 Torre De' Roveri BG Italy
+39.035.4500002 e-mail:sales@primaxint.com
primaxint.com
PI/VAT 04401680162 – a Socio Unico

EC Certificate Full Quality Assurance System: Certificate ES19/85995.00

The management system of

Radiología S.A.

Polígono Industrial Rio de Janeiro C/ Pelaya, 9-13
28110 Algete, Madrid. Spain

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2, 3, 4, 5, 6, 7 and 8 of this certificate.

This certificate is valid from 26 June 2020 until 19 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 25 September 1998
and first certified by SGS Belgium NV since 30 June 2019

Multiple certificates have been issued for this scope.
The main certificate is numbered ES19/85995.00.

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered ES/MAD 2019000881

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

X-Ray Generator RST:
RST-1010, RST-1015, RST-1020, RST-1025, RST-1030, RST-1035,
RST-1610, RST-1615, RST-1620, RST-1625. RST-1630. RST-1635,
RST-210, RST-215, RST-220, RST-225, RST-230, RST-235,
RST-310, RST-315, RST-320, RST-325, RST-330, RST-335,
RST-410, RST-415, RST-420, RST-425, RST-430, RST-435,
RST-510, RST-515, RST-520, RST-525, RST-530, RST-535,
RST-610, RST-615, RST-620, RST-625, RST-630, RST-635, RST-835
RST-1610 PSU, RST-1615 PSU,
RST-210 PSU, RST-215 PSU,
RST-310 PSU, RST-315 PSU,
RST-410 PSU, RST-415 PSU,
RST-510 PSU, RST-515 PSU
RST-1610-C, RST-1615-C,
RST-210-C, RST-215-C,
RST-310-C, RST-315-C,
RST-410-C, RST-415-C,
RST-510-C, RST-515-C

X-Ray Generator RSTR:
RSTR100, RSTR200, RSTR300, RSTR400, RSTR500, RSTR600, RSTR800

Battery Mobile X-Ray Unit PIONEER:
PIONEER

Battery Mobile X-ray Unit TRANSPORTIX B:
TX-20HF-Batt, TX-32HF-Batt, TX-40HF-Batt, TX-50HF-Batt
TX-20HF-B-D-C, TX-32HF-B-D-C, TX-40HF-B-D-C, TX-50HF-B-D-C
TX-20HF-B-D-TEZ, TX-32HF-B-D-TEZ, TX-40HF-B-D-TEZ, TX-50HF-B-D-TEZ
TX-20HF-B-D-FDX, TX-32HF-B-D-FDX, TX-40HF-B-D-FDX, TX-50HF-B-D-FDX
TX-20HF-B-D-FDXW, TX-32HF-B-D-FDXW, TX-40HF-B-D-FDXW, TX-50HF-B-D-FDXW

Capacitor Mobile X-ray Unit TRANSPORTIX MLP:
TX-16-MLP, TX-20-MLP, TX-32-MLP

Portable X-ray Unit TRANSPORTIX L:
TXL-2.0, TXL-4.0, TXL-8.0,
TXL-PLUS4, TXL-PLUS8,
TXL-PLUS4-APR, TXL-PLUS8-APR,
TXLW4, TXLW8,
TXL4HC, TXL8HC

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

Radiographic System UNIVERSAL X:

UNIVERSAL X BRS Composed of:
Radiographic Positioner: UNIVERSAL X BRS

UNIVERSAL X URS Composed of:
Radiographic Positioner: UNIVERSAL X URS
Control Box: UNIVERSAL X URS

UNIVERSAL X PLUS ADVANCED Composed of:
Radiographic Positioner: UNIVERSAL X PLUS ADVANCED
Control Box: UNIVERSAL X PLUS ADVANCED

Radiographic System POLYRAD PREMIUM:

POLYRAD PREMIUM Composed of:
Tube stand POLYRAD PREMIUM: POLYPRE-FMTS
Tube stand ADV POLYRAD PREMIUM: POLYPRE-FMTSSADV
Fixed height Table POLYRAD PREMIUM: POLYPRE-FWFTT-B
Elevating Table POLYRAD PREMIUM: POLYPRE-EL-B
Wall Stand, POLYRAD PREMIUM: POLYPRE-WBS
Tomography POLYRAD PREMIUM: POLYPRE-TOMO
Power Supply: BRAKE BOX R

POLYRAD PREMIUM ADVANCED AT Composed of:
Tube stand POLYRAD PREMIUM ADVANCED AT: POLYPRE-FMTSAT-ADV
Elevating Table POLYRAD PREMIUM ADVANCED AT: POLYPRE-ELAT-ADV
Wall Stand POLYRAD PREMIUM ADVANCED AT: POLYPRE-WBSAT-ADV
Wall Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: POLYPRE-TOMO-ADV

POLYRAD PREMIUM ADVANCED Composed of:
Tube stand POLYRAD PREMIUM ADVANCED: POLYPRE-FMTSTPC-ADV
Elevating Table POLYRAD PREMIUM ADVANCED: POLYPRE-ELTTPC-ADV
Wall Stand POLYRAD PREMIUM ADVANCED: POLYPRE-WBSTPC-ADV
Wall Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: POLYPRE-TOMO-ADV

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

Radiographic System POLYRAD:

POLYRAD S Composed of:
Tube stand POLYRAD S: POLY-S-FMTS
Table POLYRAD S: POLY-FWFTT
Wall Stand POLYRAD S: POLY-S-WBS
Power Supply: BRAKE BOX R

POLYRAD SE Composed of:
Tube stand POLYRAD S: POLY-S-FMTS
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET
Wall Stand POLYRAD S: POLY-S-WBS
Wall Stand POLYRAD PREMIUM: POLYPRE -WBS
Power Supply: BRAKE BOX R

Radiographic System POLYRAD PREMIUM CS:

POLYRAD PREMIUM CSAP Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: CSAP
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET-AP
Moving Elevating Table: POLYFLEX
Wall Stand POLYRAD PREMIUM NBS: NBSTILTMAP

POLYRAD PREMIUM CSAT Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: CSAT
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET-AT
Moving Elevating Table: POLYFLEX
Wall Stand POLYRAD PREMIUM NBS: NBSTILTMAT
Wall Stand Manual Tilting: TRWBS-TILT

POLYRAD PREMIUM CSST Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: CSST
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET
Moving Elevating Table: POLYFLEX
Wall Stand POLYRAD PREMIUM NBS: NBSTILTM
Wall Stand Manual Tilting: TRWBS-TILT

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

Radiographic System POLYRAD PREMIUM CSX:

POLYRAD PREMIUM CSX AP Composed of:
Ceiling Suspension POLYRAD PREMIUM CSX: CSXAP
Elevating Table POLYRAD PREMIUM NET400: NET400AP
Elevating Table POLYRAD PREMIUM NET500: NET500AP
Wall Stand POLYRAD PREMIUM CSXWS: CSXWSAP
X-Ray Generator Console: STH

X-Ray Generator Console
CTSC

Remote-controlled Table X-Ray System XCELLENCE:
XCELLENCE DYNAMIC

Mammographic System FEMINA:
FEMINA
FEMINA DIGITAL

Battery Mobile X-Ray Unit RAYBOW XE:
RAYBOW XE

Battery Mobile X-ray Unit RAYBOW B:
PM-20HF-Batt, PM-32HF-Batt, PM-40HF-Batt, PM-50HF-Batt

Battery Mobile X-ray Unit RAYBOW DR-C:
PM-20HF-B-D-C, PM-32HF-B-D-C, PM-40HF-B-D-C, PM-50HF-B-D-C

Battery Mobile X-ray Unit RAYBOW DR-T:
PM-20HF-B-D-TEZ, PM-32HF-B-D-TEZ, PM-40HF-B-D-TEZ, PM-50HF-B-D-TEZ

Battery Mobile X-ray Unit RAYBOW DR-F:
PM-20HF-B-D-FDX, PM-32HF-B-D-FDX, PM-40HF-B-D-FDX, PM-50HF-B-D-FDX
PM-20HF-B-D-FDXW, PM-32HF-B-D-FDXW, PM-40HF-B-D-FDXW, PM-50HF-B-D-FDXW

Capacitor Mobile X-ray Unit RAYBOW C:
PM-16-MLP, PM-20-MLP, PM-32-MLP

Portable X-ray Unit RAYBOW FLEX:
PPL-4.0, PPL-8.0,
PML4, PML8,
PML4-APR, PML8-APR,
PMLW4, PMLW8,
PML4HC, PML8HC

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

Radiographic System RIVIERA:
RIVIERA BRS Composed of:
Radiographic Positioner: RIVIERA X BRS

RIVIERA URS
Radiographic Positioner: RIVIERA X URS
Control Box: RIVIERA X URS

RIVIERA LP PLUS
Radiographic Positioner: RIVIERA X PLUS ADVANCED
Control Box: RIVIERA X PLUS ADVANCED

Radiographic System RIVIERA B:
RIVIERA B Composed of:
Tube stand POLYRAD PREMIUM: RIVB-FMTS
Tube stand ADV POLYRAD PREMIUM: RIVB-FMTSSADV
Fixed height Table POLYRAD PREMIUM: RIVB-FWFTT-B
Elevating Table POLYRAD PREMIUM: RIVB-EL-B
Wall Stand POLYRAD PREMIUM: RIVB-WBS
Tomography POLYRAD PREMIUM: RIVB-TOMO
Power Supply: BRAKE BOX R

RIVIERA B AT Composed of:
Tube stand POLYRAD PREMIUM ADVANCED AT: RIVB-FMTSAT-ADV
Elevating Table POLYRAD PREMIUM ADVANCED AT: RIVB-ELAT-ADV
Wall Stand POLYRAD PREMIUM ADVANCED AT: RIVB-WBSAT-ADV
Wall Bucky Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: RIVB-TOMO-ADV

RIVIERA B TPC Composed of:
Tube stand POLYRAD PREMIUM ADVANCED: RIVB-FMTSTPC-ADV
Elevating Table POLYRAD PREMIUM ADVANCED: RIVB-ELTTPC-ADV
Wall Stand POLYRAD PREMIUM ADVANCED: RIVB-WBSTPC-ADV
Wall Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: RIVB-TOMO-ADV

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

Radiographic System RIVIERA SP:
RIVIERA SP Composed of:
Tube stand POLYRAD S: RIVSP-FMTS
Table POLYRAD S: RIVSP-FWFTT
Wall Stand POLYRAD S: RIVSP-WBS
Power Supply: BRAKE BOX R

RIVIERA SPV Composed of:
Tube stand POLYRAD S: RIVSP-FMTS
Elevating Table POLYRAD PREMIUM NET: RIVSPV
Wall Stand POLYRAD S: RIVSP-WBS
Wall Stand POLYRAD PREMIUM: RIVB-WBS
Power Supply: BRAKE BOX R

Radiographic System RIVIERA CS:
RIVIERA CSAP Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSAP
Elevating Table POLYRAD PREMIUM NET: RIVSPV-AP
Moving Elevating Table: RIV-FLEX
Wall Stand POLYRAD PREMIUM NBS: RIVC-NBSTILTMAP

RIVIERA CSAT Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSAT
Elevating Table POLYRAD PREMIUM NET: RIVSPV-AT
Moving Elevating Table: RIV-FLEX
Wall Stand POLYRAD PREMIUM NBS: RIVC-NBSTILTMAT
Wall Stand Manual Tilting: TRWBS-TILT

RIVIERA CSST Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSST
Elevating Table POLYRAD PREMIUM NET: RIVSPV
Moving Elevating Table: RIV-FLEX
Wall Stand POLYRAD PREMIUM NBS: RIV-NBSTILTM
Wall Stand Manual Tilting: TRWBS-TILT

Radiographic System RIVIERA CSX:
POLYRAD PREMIUM CSX AP Composed of:
Ceiling Suspension POLYRAD PREMIUM CSX: RIV-CSXAP
Elevating Table POLYRAD PREMIUM NET400: RIVSPV400AP
Elevating Table POLYRAD PREMIUM NET500: RIVSPV500AP
Wall Stand POLYRAD PREMIUM CSXWS: CSXWSAP
X-Ray Generator Console: STH

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

X Ray Generator CONSOLE:
CTSC

Remote Control Table X-Ray System:
LEVIA

Mammographic System DULCIA:
DULCIA
DULCIA DIGITAL

X-Ray Generator RSTR:
PM-RSTR300, PM-RSTR400, PM-RSTR500, PM-RSTR600, PM-RSTR800

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facility:

Polígono Industrial Río de Janeiro, C/ Navas, 3
28110 Algete, Madrid. Spain

EC Certificate Full Quality Assurance System: Certificate ES19/85995.01

The management system of

Radiología S.A.

Polígono Industrial Rio de Janeiro C/ Pelaya, 9-13
28110 Algete, Madrid. Spain

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2, 3, 4, 5 of this certificate.

This certificate is valid from 26 June 2020 until 19 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 25 September 1998
and first certified by SGS Belgium NV since 30 June 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered ES/MAD 2019000881

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

X-Ray Generator RST:
RST-1010, RST-1015, RST-1020, RST-1025, RST-1030, RST- 1035
RST-1610, RST-1615, RST-1620, RST-1625, RST-1630, RST-1635,
RST-210, RST-215, RST-220, RST-225, RST-230, RST-235,
RST-310, RST-315, RST-320, RST-325, RST-330, RST-335
RST-410, RST-415, RST-420, RST-425, RST-430, RST-435,
RST-510, RST-515, RST-520, RST-525, RST-530, RST-535,
RST-610, RST-615, RST-620, RST-625, RST-630, RST-635, RST-835
RST-1610 PSU, RST-1615 PSU,
RST-210 PSU, RST-215 PSU,
RST-310 PSU, RST-315 PSU,
RST-410 PSU, RST-415 PSU,
RST-510 PSU, RST-515 PSU
RST-1610-C, RST-1615-C,
RST-210-C, RST-215-C,
RST-310-C, RST-315-C,
RST-410-C, RST-415-C,
RST-510-C, RST-515-C

X-Ray Generator RSTR:
RSTR100, RSTR200, RSTR300, RSTR400, RSTR500, RSTR600, RSTR800

Battery Mobile X-Ray Unit PIONEER:
PIONEER

Battery Mobile X-ray Unit TRANSPORTIX B:
TX-20HF-Batt, TX-32HF-Batt, TX-40HF-Batt, TX-50HF-Batt
TX-20HF-B-D-C, TX-32HF-B-D-C, TX-40HF-B-D-C, TX-50HF-B-D-C
TX-20HF-B-D-TEZ, TX-32HF-B-D-TEZ, TX-40HF-B-D-TEZ, TX-50HF-B-D-TEZ
TX-20HF-B-D-FDX, TX-32HF-B-D-FDX, TX-40HF-B-D-FDX, TX-50HF-B-D-FDX
TX-20HF-B-D-FDXW, TX-32HF-B-D-FDXW, TX-40HF-B-D-FDXW, TX-50HF-B-D-FDXW

Capacitor Mobile X-ray Unit TRANSPORTIX MLP:
TX-16-MLP, TX-20-MLP, TX-32-MLP

Portable X-ray Unit TRANSPORTIX L:
TXL-2.0, TXL-4.0, TXL-8.0,
TXL-PLUS4, TXL-PLUS8,
TXL-PLUS4-APR, TXL-PLUS8-APR,
TXLW4, TXLW8,
TXL4HC, TXL8HC

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Radiographic System UNIVERSAL X:
UNIVERSAL X BRS Composed of:
Radiographic Positioner: UNIVERSAL X BRS

UNIVERSAL X URS Composed of:
Radiographic Positioner: UNIVERSAL X URS
Control Box: UNIVERSAL X URS

UNIVERSAL X PLUS ADVANCED Composed of:
Radiographic Positioner: UNIVERSAL X PLUS ADVANCED
Control Box: UNIVERSAL X PLUS ADVANCED

Radiographic System POLYRAD PREMIUM:
POLYRAD PREMIUM Composed of:
Tube stand POLYRAD PREMIUM: POLYPRE-FMTS
Tube stand ADV POLYRAD PREMIUM: POLYPRE-FMTSSADV
Fixed height Table POLYRAD PREMIUM: POLYPRE-FWFTT-B
Elevating Table POLYRAD PREMIUM: POLYPRE-EL-B
Wall Stand, POLYRAD PREMIUM: POLYPRE-WBS
Tomography POLYRAD PREMIUM: POLYPRE-TOMO
Power Supply: BRAKE BOX R

POLYRAD PREMIUM ADVANCED AT Composed of:
Tube stand POLYRAD PREMIUM ADVANCED AT: POLYPRE-FMTSAT-ADV
Elevating Table POLYRAD PREMIUM ADVANCED AT: POLYPRE-ELAT-ADV
Wall Stand POLYRAD PREMIUM ADVANCED AT: POLYPRE-WBSAT-ADV
Wall Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: POLYPRE-TOMO-ADV

POLYRAD PREMIUM ADVANCED Composed of:
Tube stand POLYRAD PREMIUM ADVANCED: POLYPRE-FMTSTPC-ADV
Elevating Table POLYRAD PREMIUM ADVANCED: POLYPRE-ELTTPC-ADV
Wall Stand POLYRAD PREMIUM ADVANCED: POLYPRE-WBSTPC-ADV
Wall Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: POLYPRE-TOMO-ADV

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Radiographic System POLYRAD:
POLYRAD S Composed of:
Tube stand POLYRAD S: POLY-S-FMTS
Table POLYRAD S: POLY-FWFTT
Wall Stand POLYRAD S: POLY-S-WBS
Power Supply: BRAKE BOX R

POLYRAD SE Composed of:
Tube stand POLYRAD S: POLY-S-FMTS
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET
Wall Stand POLYRAD S: POLY-S-WBS
Wall Stand POLYRAD PREMIUM: POLYPRE -WBS
Power Supply: BRAKE BOX R

Radiographic System POLYRAD PREMIUM CS:
POLYRAD PREMIUM CSAP Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: CSAP
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET-AP
Moving Elevating Table: POLYFLEX
Wall Stand POLYRAD PREMIUM NBS: NBSTILTMAP

POLYRAD PREMIUM CSAT Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: CSAT
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET-AT
Moving Elevating Table: POLYFLEX
Wall Stand POLYRAD PREMIUM NBS: NBSTILTMAT
Wall Stand Manual Tilting: TRWBS-TILT

POLYRAD PREMIUM CSST Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: CSST
Elevating Table POLYRAD PREMIUM NET: POLYPRE-NET
Moving Elevating Table: POLYFLEX
Wall Stand POLYRAD PREMIUM NBS: NBSTILTM
Wall Stand Manual Tilting: TRWBS-TILT

Radiología S.A.

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Issue 1

Detailed scope

Radiographic System POLYRAD PREMIUM CSX:
POLYRAD PREMIUM CSX AP Composed of:
Ceiling Suspension POLYRAD PREMIUM CSX: CSXAP
Elevating Table POLYRAD PREMIUM NET400: NET400AP
Elevating Table POLYRAD PREMIUM NET500: NET500AP
Wall Stand POLYRAD PREMIUM CSXWS: CSXWSAP
X-Ray Generator Console: STH

X-Ray Generator Console:
CTSC

Remote-controlled Table X-Ray System XCELLENCE:
XCELLENCE DYNAMIC

Mammographic System FEMINA:
FEMINA
FEMINA DIGITAL

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facility:

Polígono Industrial Río de Janeiro, C/ Navas, 3
28110 Algete, Madrid. Spain

EC Certificate Full Quality Assurance System: Certificate ES19/85995.02

The management system of

Radiología S.A.

Polígono Industrial Rio de Janeiro C/ Pelaya, 9-13
28110 Algete, Madrid. Spain

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Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2, 3, 4 of this certificate.

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and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 25 September 1998
and first certified by SGS Belgium NV since 30 June 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered ES/MAD 2019000881

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Battery Mobile X-Ray Unit RAYBOW XE:
RAYBOW XE

Battery Mobile X-ray Unit RAYBOW B:
PM-20HF-Batt, PM-32HF-Batt, PM-40HF-Batt, PM-50HF-Batt

Battery Mobile X-ray Unit RAYBOW DR-C:
PM-20HF-B-D-C, PM-32HF-B-D-C, PM-40HF-B-D-C, PM-50HF-B-D-C

Battery Mobile X-ray Unit RAYBOW DR-T:
PM-20HF-B-D-TEZ, PM-32HF-B-D-TEZ, PM-40HF-B-D-TEZ, PM-50HF-B-D-TEZ

Battery Mobile X-ray Unit RAYBOW DR-F:
PM-20HF-B-D-FDX, PM-32HF-B-D-FDX, PM-40HF-B-D-FDX, PM-50HF-B-D-FDX
PM-20HF-B-D-FDXW, PM-32HF-B-D-FDXW, PM-40HF-B-D-FDXW, PM-50HF-B-D-FDXW

Capacitor Mobile X-ray Unit RAYBOW C:
PM-16-MLP, PM-20-MLP, PM-32-MLP

Portable X-ray Unit RAYBOW FLEX:
PPL-4.0, PPL-8.0,
PML4, PML8,
PML4-APR, PML8-APR,
PMLW4, PMLW8,
PML4HC, PML8HC

Radiographic System RIVIERA:
RIVIERA BRS Composed of:
Radiographic Positioner: RIVIERA X BRS

RIVIERA URS
Radiographic Positioner: RIVIERA X URS
Control Box: RIVIERA X URS

RIVIERA LP PLUS
Radiographic Positioner: RIVIERA X PLUS ADVANCED
Control Box: RIVIERA X PLUS ADVANCED

Radiología S.A.

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on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Radiographic System RIVIERA B:

RIVIERA B Composed of:
Tube stand POLYRAD PREMIUM: RIVB-FMTS
Tube stand ADV POLYRAD PREMIUM: RIVB-FMTSSADV
Fixed height Table POLYRAD PREMIUM: RIVB-FWFTT-B
Elevating Table POLYRAD PREMIUM: RIVB-EL-B
Wall Stand POLYRAD PREMIUM: RIVB-WBS
Tomography POLYRAD PREMIUM: RIVB-TOMO
Power Supply: BRAKE BOX R

RIVIERA B AT Composed of:
Tube stand POLYRAD PREMIUM ADVANCED AT: RIVB-FMTSAT-ADV
Elevating Table POLYRAD PREMIUM ADVANCED AT: RIVB-ELAT-ADV
Wall Stand POLYRAD PREMIUM ADVANCED AT: RIVB-WBSAT-ADV
Wall Bucky Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: RIVB-TOMO-ADV

RIVIERA B TPC Composed of:
Tube stand POLYRAD PREMIUM ADVANCED: RIVB-FMTSTPC-ADV
Elevating Table POLYRAD PREMIUM ADVANCED: RIVB-ELTTPC-ADV
Wall Stand POLYRAD PREMIUM ADVANCED: RIVB-WBSTPC-ADV
Wall Stand Manual Tilting: TRWBS-TILT
Tomography POLYRAD PREMIUM ADVANCED: RIVB-TOMO-ADV

Radiographic System RIVIERA SP:

RIVIERA SP Composed of:
Tube stand POLYRAD S: RIVSP-FMTS
Table POLYRAD S: RIVSP-FWFTT
Wall Stand POLYRAD S: RIVSP-WBS
Power Supply: BRAKE BOX R

RIVIERA SPV Composed of:
Tube stand POLYRAD S: RIVSP-FMTS
Elevating Table POLYRAD PREMIUM NET: RIVSPV
Wall Stand POLYRAD S: RIVSP-WBS
Wall Stand POLYRAD PREMIUM: RIVB-WBS
Power Supply: BRAKE BOX R

Radiología S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).
Issue 1

Detailed scope

Radiographic System RIVIERA CS:
RIVIERA CSAP Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSAP
Elevating Table POLYRAD PREMIUM NET: RIVSPV-AP
Moving Elevating Table: RIV-FLEX
Wall Stand POLYRAD PREMIUM NBS: RIVC-NBSTILTMAP

RIVIERA CSAT Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSAT
Elevating Table POLYRAD PREMIUM NET: RIVSPV-AT
Moving Elevating Table: RIV-FLEX
Wall Stand POLYRAD PREMIUM NBS: RIVC-NBSTILTMAT
Wall Stand Manual Tilting: TRWBS-TILT

RIVIERA CSST Composed of:
Ceiling Suspension POLYRAD PREMIUM CS: RIV-CSST
Elevating Table POLYRAD PREMIUM NET: RIVSPV
Moving Elevating Table: RIV-FLEX
Wall Stand POLYRAD PREMIUM NBS: RIV-NBSTILTM
Wall Stand Manual Tilting: TRWBS-TILT

Radiographic System RIVIERA CSX:
POLYRAD PREMIUM CSX AP Composed of:
Ceiling Suspension POLYRAD PREMIUM CSX: RIV-CSXAP
Elevating Table POLYRAD PREMIUM NET400: RIVSPV400AP
Elevating Table POLYRAD PREMIUM NET500: RIVSPV500AP
Wall Stand POLYRAD PREMIUM CSXWS: CSXWSAP
X-Ray Generator Console: STH

X Ray Generator CONSOLE:
CTSC
Remote Control Table X-Ray System:
LEVIA
Mammographic System DULCIA:
DULCIA
DULCIA DIGITAL
X-Ray Generator RSTR:
PM-RSTR300, PM-RSTR400, PM-RSTR500, PM-RSTR600, PM-RSTR800

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facility
Polígono Industrial Río de Janeiro, C/ Navas, 3
28110 Algete, Madrid. Spain

CERTIFICATE OF AUTHORIZATION

We hereby certify that:

Violin Savca

of

SRL VIPROMED SERVICE

has been trained in Installation, Configuration, Calibration and Maintenance of our products proposed.

Yours Sincerely,

Massimo Cavallaro

Managing Director

primax INTERNATIONAL Via Volta, 10, 24060 TORRE DE' ROVERI (BERGAMO) - ITALY PI/VAT 04401680162

Via A. Volta, 10 24060 Torre De' Roveri BG Italy
+39.035.4500002 e-mail:sales@primaxint.com
primaxint.com
PI/VAT 04401680162

Torre de' Roveri, 10.11.2023

Letter of Authorization for Authorized Representatives

Dear Sir/Madam,

Subject: **Letter of Authorization for SRL VIPROMED SERVICE**

We, **PRIMAX INTERNATIONAL Srl** as the Product Owner, hereby authorize SRL VIPROMED SERVICE as our products authorized distributor in the territory of Republic of Moldova.

We authorize SRL VIPROMED SERVICE to:

- Arrange importation and registration of our products according to legal requirements of regulatory bodies and appropriate government institutions in the territory of Republic of Moldova to ensure maximum success of the marketing of our products.
- Use for marketing purposes the trade name, technical specifications, description, and pictures of our products.
- Participate in various tenders.
- Provide the servicing and repairing to our equipment.

This authorization shall apply to the following medical devices:

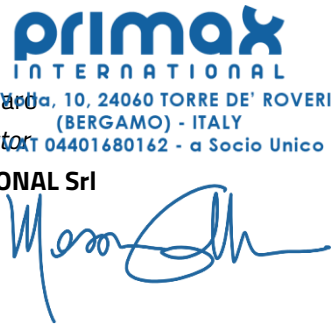
1. Cyberbloc FP-S
2. Raybow XE
3. Raybow Flex DR

Via A. Volta, 10 24060 Torre De' Roveri BG Italy
+39.035.4500002 e-mail:sales@primaxint.com
primaxint.com
PI/VAT 04401680162 – a Socio Unico

This authorization shall remain until the 31st of December 2024.

Yours Sincerely,

Massimo Cavallaro
Managing Director
PRIMAX INTERNATIONAL Srl



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