

EU Quality Management System Certificate ES24/00000401

The management system of

RADIOLOGÍA, S.A.



C/ Pelaya, 13 Polígono Industrial Rio de Janeiro 28110 ALGETE (Madrid). Spain
SRN Number: ES-MF-000025671

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 16 April 2025 until 24 April 2029 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 24 October 2028

Issue 2. Certified since 23 April 2024

Authorised by

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Certification Manager

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MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIb devices:
MDA0201, MDS1009;

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
(EMDN: Z11039011; Basic UDI-DI: 843657959GENERATOR6H)

X-Ray Generator RSTR:

RSTR100, RSTR200, RSTR300, RSTR400, RSTR500, RSTR600, RSTR800
(EMDN: Z11039011; Basic UDI-DI: 843657959GENERATOR6H)

Battery Mobile X-Ray Unit PIONEER:

PIONEER
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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Capacitor Mobile X-ray Unit TRANSPORTIX MLP:

TX-16-MLP, TX-20-MLP, TX-32-MLP

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Capacitor Mobile X-Ray Unit:

PIONEER C

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Battery Portable X-Ray Unit:

SPARK

SPARK-XS

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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

(EMDN: Z11039005; Basic UDI-DI: 843657959UNIVERSALPK)



RADIOLOGÍA, S.A.

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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
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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)



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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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

X-Ray Generator Console:

CTSC
(EMDN: Z11039006; Basic UDI-DI: 843657959CONSOLE9P)

X-Ray Remote Controlled System:

XCELLENCE DYNAMIC
(EMDN: Z11039005; Basic UDI-DI: 843657959REMOTETABLEA5)

Mammographic System FEMINA:

FEMINA
(EMDN: Z11030201; Basic UDI-DI: 843657959MAMOSYSTEME6)
FEMINA DIGITAL
(EMDN: Z11030202; Basic UDI-DI: 843657959MAMOSYSTEME6)

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Battery Mobile X-Ray Unit RAYBOW XE:

RAYBOW XE

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Battery Mobile X-ray Unit RAYBOW B:

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

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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 (EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Capacitor Mobile X-ray Unit RAYBOW C:

PM-16-MLP, PM-20- MLP, PM-32-MLP

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Capacitor Mobile X-Ray Unit:

RAYBOW LYRA

(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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Portable X-ray Unit RAYBOW FLEX:

PPL-4.0, PPL-8.0,
PML4, PML8,
PML4-APR, PML8-APR,
PMLW4, PMLW8,
PML4HC, PML8HC
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Battery Portable X-Ray Unit:

RAYBOW MOON
RAYBOW FLEX BP
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Radiographic System RIVIERA:

RIVIERA BRS Composed of:
Radiographic Positioner: RIVIERA X BRS

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

RIVIERA LP PLUS Composed of
Radiographic Positioner: RIVIERA X PLUS ADVANCED
Control Box: RIVIERA X PLUS ADVANCED
(EMDN: Z11039005; Basic UDI-DI: 843657959UNIVERSALPK)

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

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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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

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: RIV-NBSTILTMAP



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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: RIV-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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

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
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

X-Ray Generator Console:

CTSC
(EMDN: Z11039006; Basic UDI-DI: 843657959CONSOLE9P)

X-Ray Remote Controlled System:

LEVIA
(EMDN: Z11039005; Basic UDI-DI: 843657959REMOTETABLEA5)

X-Ray Generator RSTR:

PM-RSTR300, PM-RSTR400, PM-RSTR500, PM-RSTR600, PM-RSTR800
(EMDN: Z11039011; Basic UDI-DI: 843657959GENERATOR6H)

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X-ray generators, Type HF:

N32HF (option 3M25), N32HF (option 3M20), N32HF (option 3T25),
N32HF (option 3T20), N32HF (option 3T35), N32HF (option 3T30),
N40HF (option 4M25), N40HF (option 4M20), N40HF (option 4T25),
N40HF (option 4T20), N40HF (option 4T35), N40HF (option 4T30),
N50HF (option 5M25), N50HF (option 5M20), N50HF (option 5T25),
N50HF (option 5T20), N50HF (option 5T35), N50HF (option 5T30),
N65HF (option 6T35), N65HF (option 6T30), N80HF (option 8T30)
N16HFC (option 16M25C), N16HFC (option 16M20C),
N20HFC (option 2M25C), N20HFC (option 2M20C),
N32HFC (option 3M25C), N32HFC (option 3M20C), N40HFC (option 4M25C),
N40HFC (option 4M20C), N50HFC (option 5M25C), N50HFC (option 5M20C)
N32HFR (option 3M25R), N32HFR (option 3M20R), N40HFR (option 4M25R),
N40HFR (option 4M20R), N50HFR (option 5M25R), N50HFR (option 5M20R)
(EMDN: Z11039011; Basic UDI-DI: 843657959GENERATOR6H)

X-ray generators, Type HF-N:

N10HF-N, N20HF-N, N32HF-N, N40HF-N, N50HF-N, N65HF-N, N80HF-N
(EMDN: Z11039011; Basic UDI-DI: 843657959GENERATOR6H)

Battery Mobile X-ray Unit Dreamy:

MOVIX Dreamy
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Battery Mobile X-ray unit:

MOVIX 20, MOVIX 30, MOVIX 40, MOVIX 50
MOVIX 20 DReam C, MOVIX 30 DReam C, MOVIX 40 DReam C, MOVIX 50 DReam C,
MOVIX 20 DReam T (Option W), MOVIX 30 DReam T (Option W),
MOVIX 40 DReam T (Option W), MOVIX 50 DReam T (Option W),
MOVIX 20 DReam Ta, MOVIX 30 DReam Ta, MOVIX 40 DReam Ta,
MOVIX 50 DReam Ta,
MOVIX 20 DReam Ta (Option W), MOVIX 30 DReam Ta (Option W), MOVIX 40 DReam Ta (Option W),
MOVIX 50 DReam Ta (Option W),
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Capacitor Mobile X-ray Unit:

MOVIX 16 E+, MOVIX 20 E+, MOVIX 30 E+.
MOVIX PRIME
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

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Portable X-Ray Unit:

PDR 4.0, PDR 8.0,
MOVIX 4.0 E+, MOVIX 8.0 E+,
MOVIX 4.0 E+ (option APR), MOVIX 8.0 E+ (option APR).
MOVIX 4.0 E+ DReam, MOVIX 8.0 E+ DReam,
MOVIX 4.0 E+ DReam (option HC), MOVIX 8.0 E+ DReam (option HC),
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Battery Portable X-Ray Unit:

MOVIX PMC
PDR-E+
(EMDN: Z11039016; Basic UDI-DI: 843657959MOBILEW4)

Multipurpose radiographic system:

BRS Composed of:
Radiographic Positioner: BRS
STATIF STUM Composed of:
Radiographic Positioner: STATIF STUM
Control Box: STATIF STUM

STATIF PRO Composed of:
Radiographic Positioner: STATIF PRO
Control Box: STATIF PRO
(EMDN: Z11039005; Basic UDI-DI: 843657959UNIVERSALPK)

Radiographic System RAD Series PRO:

RAD Series PRO composed of:
Elevating floating table top TPF3S,
Floating table top TPF2S,
Floor mounted tubestand: C2RS or C2RS (option AD),
Vertical bucky stand PM2S,
Tomography: TOMO RAD PRO

RAD Series PRO (Option AT) composed of:
Floor mounted tubestand: C2RS (option AT), Vertical bucky stand: PM2S (option AT),
Elevating floating table top: TPF3S (option AT),
Tomography: TOMO RAD PRO (option PLUS),
Vertical bucky stand: PMB3S

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RAD Series PRO (Option TPC) composed of:
Floor mounted tubestand: C2RS (option TPC),
Vertical bucky stand: PM2S (option TPC),
Elevating floating table top: TPF3S (option TPC),
Tomography: TOMO RAD PRO (option PLUS),
Vertical bucky stand: PMB3S
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

Radiographic System RAD Series E+:

RAD Series E+ composed of:
Floating table top: TPF1S,
Floor mounted tubestand: C1HR,
Vertical bucky stand: PM1S

RAD Series E+ (option HV) composed of:
Elevating floating table top: TPF4S,
Floor mounted tubestand: C1HR,
Vertical bucky stand: PM1S or PM2S
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

Radiographic System Xtreme:

Xtreme composed of:
Ceiling tubestand: SP4S,
Elevating floating table top: TPF4S,
Floating table top: TW4S,
Vertical bucky stand: PMB4S or PMB3S

Xtreme (option AT) composed of:
Ceiling tubestand: SP4S (option AT),
Elevating floating table top: TPF4S (option AT),
Floating table top: TW4S,
Vertical bucky stand: PMB4S (option AT) or PMB3S



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Xtreme (option AP) composed of:
Ceiling tubestand: SP4S (option AP),
Elevating floating table top: TPF4S (option AP),
Floating table top: TW4S,
Vertical bucky stand: PMB4S (option AP)
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

Radiographic System Xtreme Premium:

Xtreme Premium composed of:
Ceiling tubestand: SP4S Premium,
Elevating floating table top: TPF4S Premium or TPF5S Premium,
Vertical bucky stand: PMB4S Premium,
X-Ray Generator Console (optional): STH
(EMDN: Z11039005; Basic UDI-DI: 843657959SYSTEM9C)

X-Ray Generator Console:

ETAC
(EMDN: Z11039006; Basic UDI-DI: 843657959CONSOLE9P)

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - ES/MAD/300003519 - CTC

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

Change in between this certificate and previous one: scope amendment - initial certification of X-ray devices, scope change, new trademarks

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