

Radiología S.A.

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

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

Authorised by



Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

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LPMD5105 – Corrigendum to Certificate

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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

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 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-

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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-FMST
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-FMST
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: NBSTILTMAT

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: NBSTILTMAT
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

X-Ray Generator Console:
CTSC

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

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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

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

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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

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- NBSTILTMAT

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:

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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-RaySystem:
 LEVIA

Mammographic System DULCIA:
 DULCIA
 DULCIA DIGITAL

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

This corrigendum is only valid together with accompanying 93/42/EEC certificate ES19/85995.00
 Issue 3

Correction date	Correction
Change approved by SGS on 07 February 2023	<p>Several changes implemented after on-site surveillance audit of Nov 2022 & applicable to main MDD certificate ES19/85995.00 and child certificates ES19/85995.01 and ES19/85995.02.</p> <ul style="list-style-type: none"> • Identification of the company amended to "RADIOLOGÍA S.A." instead of "Radiología S.A." to exactly match with official registers. • Rewording of company address putting first the street (C/ Pelaya 13) and after that the Industrial Area (Polígono Industrial Rio de Janeiro): C/ Pelaya, 13 Polígono Industrial Rio de Janeiro 28110 ALGETE (Madrid) - Spain <p>• Scope amendments: - Family "Remote-controlled Table X-Ray System XCELLENCE: XCELLENCE DYNAMIC" reworded to "X-Ray Remote</p>

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	<p>Controlled System XCELLENCE: XCELLENCE DYNAMIC”.</p> <ul style="list-style-type: none"> - Family “Remote Control Table X-Ray System: LEVIA” reworded to “X-Ray Remote Controlled System: LEVIA”. - Mammographic System DULCIA is removed from certification as per client’s decision. - Family Radiographic System RIVIERA, wording “composed of” added after RIVIERA URS and RIVIERA LP PLUS.
Change approved by SGS on 27 November 2023	<ul style="list-style-type: none"> • Scope amendments: <ul style="list-style-type: none"> - New trade names approved to be added to main MDD certificate ES19/85995.00: <p>X-ray generators, Type HF:</p> <p>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)</p> <p>X-ray generators, Type HF-N:</p> <p>N10HF-N, N20HF-N, N32HF-N, N40HF-N, N50HF-N, N65HF-N, N80HF-N</p> <p>Battery Mobile X-ray Unit Dreamy:</p>

	<p>MOVIX Dreamy</p> <p>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),</p> <p>Capacitor Mobile X-ray Unit: MOVIX 16 E+, MOVIX 20 E+, MOVIX 30 E+</p> <p>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),</p> <p>Multipurpose radiographic system: BRS Composed of: Radiographic Positioner: BRS</p> <p>STATIF STUM Composed of: Radiographic Positioner: STATIF STUM Control Box: STATIF STUM</p> <p>STATIF PRO Composed of: Radiographic Positioner: STATIF PRO Control Box: STATIF PRO</p> <p>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),</p>
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	<p>Vertical bucky stand PM2S, Tomography: TOMO RAD PRO</p> <p>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</p> <p>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</p> <p>Radiographic System RAD Series E+: RAD Series E+ composed of: Floating table top: TPF1S, Floor mounted tubestand: C1HR, Vertical bucky stand: PM1S</p> <p>RAD Series E+ (option HV) composed of: Elevating floating table top: TPF4S, Floor mounted tubestand: C1HR, Vertical bucky stand: PM1S or PM2S</p> <p>Radiographic System Xtreme: Xtreme composed of: Ceiling tubestand: SP4S, Elevating floating table top: TPF4S, Floating table top: TW4S, Vertical bucky stand: PMB4S or PMB3S</p> <p>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</p> <p>Xtreme (option AP) composed of:</p>
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	<p>Ceiling tubestand: SP4S (option AP), Elevating floating table top: TPF4S (option AP), Floating table top: TW4S, Vertical bucky stand: PMB4S (option AP)</p> <p>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</p> <p>X-Ray Generator Console: ETAC</p>
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