

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

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Certificate ES19/85995.00 continued

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

Certificate ES19/85995.00 continued

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

Certificate ES19/85995.00 continued

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: 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: 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

Certificate ES19/85995.00 continued

Radiología S.A.

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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.

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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-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:

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

Certificate ES19/85995.00 continued

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.

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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

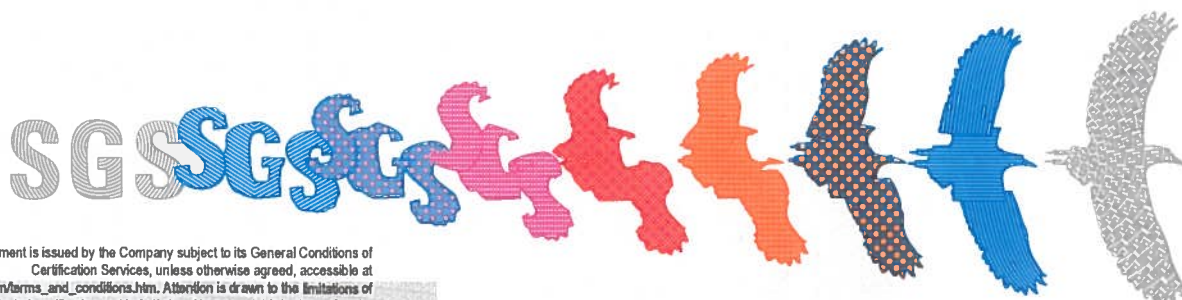


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SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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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

Certificate ES19/85995.01 continued

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

Certificate ES19/85995.01 continued

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-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

Certificate ES19/85995.01 continued

Radiología S.A.

Directive 93/42/EEC

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

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:

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EC Certificate Full Quality Assurance System: Certificate ES19/85995.02

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Authorised by

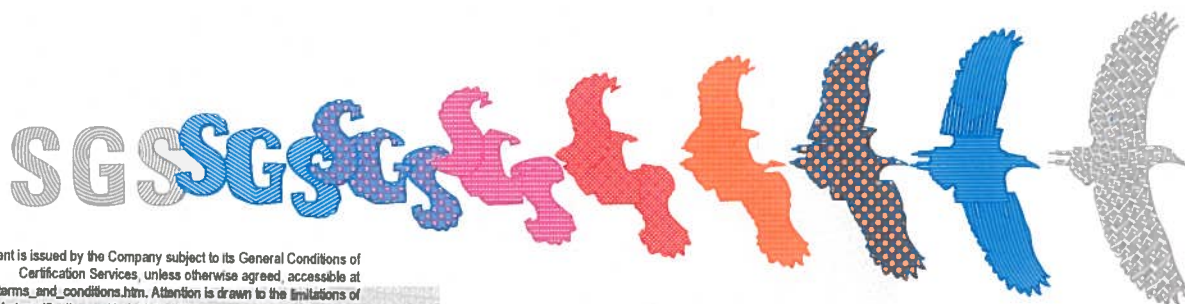


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SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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Certificate ES19/85995.02 continued

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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

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Radiología S.A.

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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

Certificate ES19/85995.02 continued

Radiología S.A.

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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