

Sociedad Española de Electromedicina y Calidad, S.A. (SEDECAL)

Poligono 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 of this certificate.

This certificate is valid from 08 December 2020 until 19 July 2023
and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 20 May 1997

and first certified by SGS Belgium NV since 30 June 2019

Certification is based on reports numbered ES/MAD 2019000881

Authorised by

SGS Belgium NV, Notified Body 1639

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Detailed scope

X-Ray Generator SHF:

SHF-1010, SHF-1015, SHF-1020, SHF-1025, SHF-1030, SHF-1035,
SHF-1610, SHF-1615, SHF-1620, SHF-1625, SHF-1630, SHF-1635,
SHF-210, SHF-215, SHF-220, SHF-225, SHF-230, SHF-235,
SHF-310, SHF-315, SHF-320, SHF-325, SHF-330, SHF-335,
SHF-410, SHF-415, SHF-420, SHF-425, SHF-430, SHF-435,
SHF-510, SHF-515, SHF-520, SHF-525, SHF-530, SHF-535,
SHF-610, SHF-615, SHF-620, SHF-625, SHF-630, SHF-635, SHF-835,
SHF-1610 PSU, SHF-1615 PSU,
SHF-210 PSU, SHF-215 PSU,
SHF-310 PSU, SHF-315 PSU,
SHF-410 PSU, SHF-415 PSU, SHF-510 PSU, SHF-515 PSU
SHF-1610-C, SHF-1615-C,
SHF-210-C, SHF-215-C,
SHF-310-C, SHF-315-C,
SHF-410-C, SHF-415-C,
SHF-510-C, SHF-515-C
SHF-0510-M, SHF-0530-M, SHF-1010-M, SHF-1030-M,
SHF-0510-MPSTA, SHF-1010-MPSTA

X-Ray Generator SHFR:

SHFR100, SHFR200, SHFR300, SHFR400, SHFR500, SHFR600, SHFR800

Battery Mobile X-Ray Generator:

SM-IV

Battery Mobile X-Ray Unit PHOENIX:

PHOENIX

Battery Mobile X-Ray Unit EASY MOVING:

SM-20HF-Batt, SM-32HF-Batt, SM-40HF-Batt, SM-50HF-Batt
SM-20HF-B-D-C, SM-32HF-B-D-C, SM-40HF-B-D-C, SM-50HF-B-D-C
SM-20HF-B-D-TEZ, SM-32HF-B-D-TEZ, SM-40HF-B-D-TEZ, SM-50HF-B-D-TEZ
SM-20HF-B-D-FDX, SM-32HF-B-D-FDX, SM-40HF-B-D-FDX, SM-50HF-B-D-FDX
SM-20HF-B-D-FDXW, SM-32HF-B-D-FDXW, SM-40HF-B-D-FDXW,
SM-50HF-B-D-FDXW
SM-20HF-B-D-KM (AeroDR X30), SM-32HF-B-D-KM (AeroDR X30),
SM-40HF-B-D-KM (AeroDR X30), SM-50HF-B-D-KM (AeroDR X30)

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Capacitor Mobile X-Ray Unit MOBIXRAY:
SMR-16, SMR-20, SMR-32

Portable X-Ray Unit SPL:
SPL-HF-2.0, SPL-HF-4.0, SPL- HF-8.0

Portable X-Ray Unit DRAGON X:
SPSL-HF-4.0, SPSL-HF-8.0,
SPSL-HF-4.0-APR, SPSL-HF-8.0- APR,
SPSLW4, SPSLW8 SPSL4HC, SPSL8HC

Radiographic System SEDECAL X:
SEDECAL X BRS (BRX) Composed of:
Radiographic Positioner: SEDECAL X BRS (BRX)

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

SEDECAL X PLUS LP PLUS Composed of:
Radiographic Positioner: SEDECAL X PLUS LP PLUS
Control Box: SEDECAL X PLUS LP PLUS

Radiographic System MILLENNIUM:
MILLENNIUM, Composed of:
Tube stand MILLENNIUM: MILL- FMTS
Tube stand MILLENNIUM: MILL- FMTS-TS
Tube stand AD MILLENNIUM: MILL-FMTSAD
Fixed height Table MILLENNIUM: MILL-FWFTT-B
Elevating Table MILLENNIUM: MILL-EL-B
Wall Stand MILLENNIUM: MILL- WBS
Wall Stand MILLENNIUM: MILL- WBS-TS
Tomography MILLENNIUM: MILL- TOMO
Power Supply: BRAKE BOX

MILLENNIUM PLUS AT, Composed of:
Tube stand MILLENNIUM PLUS AT: MILL-FMTSAT-PLUS
Elevating Table MILLENNIUM PLUS AT: MILL-ELAT-PLUS
Wall Stand MILLENNIUM PLUS AT: MILL-WBSAT-PLUS
Wall Stand Manual Tilting: TWBS- TILT
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS

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MILLENNIUM PLUS TPC, Composed of:
Tube stand MILLENNIUM PLUS TPC: MILL-FMTSTPC-PLUS
Elevating Table MILLENNIUM PLUS TPC: MILL-ELTPC-PLUS
Wall Stand MILLENNIUM PLUS TPC: MILL-WBSTPC-PLUS
Wall Stand Manual Tilting: TWBS- TILT
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS

Radiographic System PROTEUS XR/f:

PROTEUS XR/f ET, Composed of:
Tube stand MULTIRAD: MULT-FMFS
Elevating Table NET 4000: NET 4000-ST
Wall Stand MILLENIUM: MILL-WBS

PROTEUS XR/f AT, Composed of:
Tube stand MILLENNIUM PLUS AT: MILL-FMFSAT-PLUS
Elevating Table MILLENNIUM PLUS AT: MILL-ELAT-PLUS
Wall Stand MILLENNIUM PLUS AT: MILL-WBSAT-PLUS
Wall Stand Manual Tilting: TWBS- TILT
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS

PROTEUS XR/f ST, Composed of:
Tube stand MULTIRAD: MULT-FMFS
Table MULTIRAD: MULT-FWFTD
Wall Stand MILLENIUM: MILL-WBS

Radiographic System MULTIRAD:

MULTIRAD (Proteus), Composed of:
Tube stand MULTIRAD: MULT- FMFS
Table MULTIRAD: MULT-FWFTT
Wall Stand MULTIRAD: MULT- WBS
Power Supply: BRAKE BOX

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MULTIRAD NET, Composed of:

Tube stand MULTIRAD: MULT- FMTS
Elevating Table NET 4000: NET 4000-ST
Wall Stand MULTIRAD: MULT- WBS
Wall Stand MILLENNIUM: MILL- WBS
Power Supply: BRAKE BOX

Radiographic System NOVA:

NOVA FA Composed of:

Ceiling Suspension NOVA: NOVA FA
Elevating Table NET 4000: NET 4000-AU
Moving Elevating Table: FLEXI- DT
Wall Stand NBS 2100: NBS 2100-AU

NOVA AT Composed of:

Ceiling Suspension NOVA: NOVA AT
Elevating Table NET 4000: NET 4000-AT
Moving Elevating Table: FLEXI- DT
Wall Stand NBS 2100: NBS 2100- AT
Wall Stand Manual Tilting: TWBS- TILT

NOVA ST Composed of:

Ceiling Suspension NOVA: NOVA ST
Elevating Table NET 4000: NET 4000-ST
Moving Elevating Table: FLEXI- DT
Wall Stand NBS 2100: NBS 2100- ST
Wall Stand Manual Tilting: TWBS- TILT

Radiographic System CHALLENGE X:

CHALLENGEX AP Composed of:

Ceiling Suspension CHALLENGE X: CHAP
Elevating Table NET400: NET400AP
Elevating Table NET500: NET500AP
Wall Stand CHALLENGE X: CHWSAP

X-Ray Generator Console:

X Ray Generator Console: CTSC

Ozone Generator:

OM-302, OM302E, OM302IE, OM302IU, OM302IJ
OZONOBARIC P
OZONETTE

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.