

EC Certificate Full Quality Assurance System: ES97/9864

The management system of

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

C/ Pelaya, 9-13
Polígono Industrial Rio de Janeiro
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 29 January 2016 until 19 July 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 20 July 2018
Issue 49. Certified since 20 May 1997

Certification is based on reports numbered ES/MAD 133585

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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Page 1 of 8



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

Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 49

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

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

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 49

X-Ray Generator SHFR:

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

X-Ray Generator HERCULES:

HERCULES-32, HERCULES-40, HERCULES-50, HERCULES-65,
HERCULES-80

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-V, SM-32HF-B-D-V, SM-40HF-B-D-V, SM-50HF-B-D-V
SM-20HF-B-D-T, SM-32HF-B-D-T, SM-40HF-B-D-T, SM-50HF-B-D-T
SM-20HF-B-D-TEZ, SM-32HF-B-D-TEZ, SM-40HF-B-D-TEZ,
SM-50HF-B-D-TEZ
SM-20HF-B-D-S, SM-32HF-B-D-S, SM-40HF-B-D-S, SM-50HF-B-D-S
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)

Capacitor Mobile X-Ray Unit MOBIXRAY:

SMR-16, SMR-20, SMR-32

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

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)

Issue 49

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-D, SPSL-HF-8.0-D,
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),
SEDECAL X URS,
SEDECAL X PLUS LP,
SEDECAL X PLUS LP PLUS

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

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 49

Radiographic System MILLENNIUM:

MILLENNIUM (Proteus XR/i), Composed of:

Tube stand MILLENNIUM: MILL-FMTS

Tube stand AD MILLENNIUM: MILL-FMTSAD

Fixed height Table MILLENNIUM: MILL-FWFTT-B

Elevating Table MILLENNIUM: MILL-EL-B

Wall Stand MILLENNIUM: MILL-WBS

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

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

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

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 49

Radiographic System MULTIRAD:

MULTIRAD (Proteus XR/e), Composed of:

Tube stand MULTIRAD: MULT-FMS

Table MULTIRAD: MULT-FWFTT

Wall Stand MULTIRAD: MULT-WBS

Power Supply: BRAKE BOX

MULTIRAD NET, Composed of:

Tube stand MULTIRAD: MULT-FMS

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

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

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 49

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

X-Ray Generator Console:

TPC 12", CTSC

**Ozone Generators for ozonotherapy applications in conditions such as
osteoarticular pathologies, pain management and diabetic foot:**

OM-302, OM302E, OM302IE, OM302IU, OM302IJ

OZONOBARIC P

OZONETTE

EC Certificate Full Quality Assurance System: ES97/9864, continued

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Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)

Issue 49

Radiographic Unit Control Software:

SedewareControl1

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