

EC Certificate Full Quality Assurance System: Certificate ES19/85990

The management system of

# 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 the subsequent pages  
of this certificate**

This certificate is valid from 30/06/2019 until 19/07/2023  
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 20/05/1997

and first certified by SGS Belgium on 30/06/2019.


Re certification audit due before 19/07/2021

This is a multi-site certification.

Additional site details are listed on subsequent pages

Certification is based on reports numbered ES/MAD 133585

Authorised by



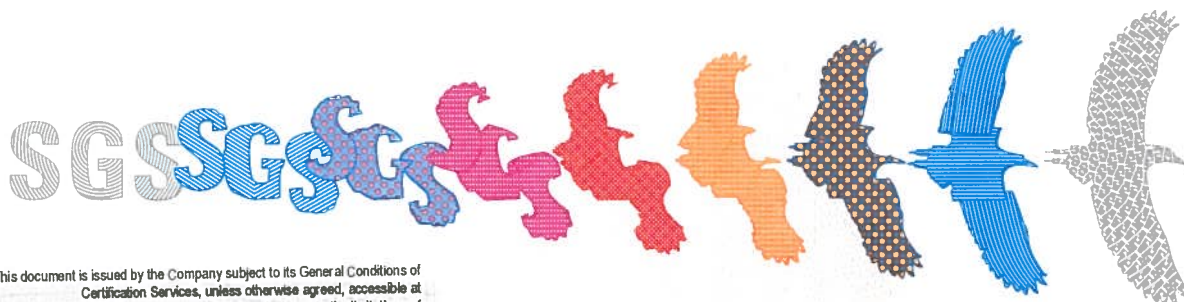
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Certification Manager

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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 1

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

### 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)

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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),  
SEDECAL X URS,  
SEDECAL X PLUS LP,  
SEDECAL X PLUS LP PLUS

### 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

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Issue 1

Detailed scope

### Radiographic System PROTEUS XR/f:

PROTEUS XR/f ET, Composed of:

Tube stand MILLENNIUM: MILL-FMFS

Tube stand AD MILLENNIUM: MILL-FMFSAD

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

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-FMS

Table MULTIRAD: MULT-FWFTT

Wall Stand MULTIRAD: MULT-WBS

Power Supply: BRAKE BOX

### 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

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### 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

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### 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: STH

#### X Ray Generator Console:

CTSC

#### Radiographic Unit Control Software:

SedewareControl1

Additional facilities

**Polígono Industrial Río de Janeiro**  
**C/ Rafael Pillado Mourelle, 6 Nave C-5**  
**28110 Algete, Madrid. Spain**

**Polígono Industrial Río de Janeiro**  
**C/ Navas, 3**  
**28110 Algete, Madrid. Spain**