

EU Quality Management System Certificate ES23/00000120

The management system of



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

C/ Pelaya 9, Polígono Industrial Rio de Janeiro, 28110 Algete (Madrid). Spain.
SRN Number: ES-MF-000017998

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2, 3, 4, 5 and 6 of this certificate

This certificate is valid from 21 January 2025 until 06 February 2028 and remains valid subject to satisfactory surveillance audits.

Re certification due before 06 August 2027

Issue 6. Certified since 06 February 2023

Authorised by

Virginie Siloret

Global Medical Device
Certification Manager

SGS Belgium NV NB1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 - www.sgs.com

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Management System Certificate ES23/00000120,
continued



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

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIb devices:
MDA0201, MDS1009;

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
(EMDN: Z11039011; Basic UDI-DI: 843604600GENERATORBD)

X-Ray Generator SHFR:

SHFR100, SHFR200, SHFR300, SHFR400, SHFR500, SHFR600, SHFR800
(EMDN: Z11039011; Basic UDI-DI: 843604600GENERATORBD)

Mobile X-Ray Generator:

SM-IV
SM-V
SPSB
SPB
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILEGENCG)

Battery Mobile X-Ray Unit PHOENIX:

PHOENIX
Mobirex+
AeroDR TX m01
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

This document is an authentic electronic certificate for Client's business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Management System Certificate ES23/00000120,
continued



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

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

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)
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Capacitor Mobile X-Ray Unit MOBIXRAY:

SMR-16, SMR-20, SMR-32
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Capacitor Mobile X-Ray Unit:

PrimeX
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Portable X-Ray Unit SPL:

SPL-HF-2.0, SPL-HF-4.0, SPL-HF-8.0
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

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
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Battery Portable X-Ray Unit.

Pegasus
CYCLOPS
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Radiographic System SEDECAL X:

SEDECAL X BRS, Composed of:
Radiographic Positioner: SEDECAL X BRS

This document is an authentic electronic certificate for Client's business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Management System Certificate ES23/00000120,
continued



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

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

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
(EMDN: Z11039005; Basic UDI-DI: 843604600UNIVERSALUF)

Radiographic System MILLENNIUM:

MILLENNIUM, Composed of:
Tube Stand MILLENNIUM: MILL-FMFS
Tube Stand MILLENNIUM: MILL-FMFS-TS
Tube Stand AD MILLENNIUM: MILL-FMFSAD
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-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

MILLENNIUM PLUS TPC, Composed of:
Tube Stand MILLENNIUM PLUS TPC: MILL-FMFSAT-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
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

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 MILLENNIUM: MILL-WBS

This document is an authentic electronic certificate for Client's business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Management System Certificate ES23/00000120,
continued

SGS

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

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

PROTEUS XR/f ST, Composed of:
Tube Stand MULTIRAD: MULT-FMTS
Table MULTIRAD: MULT-FWFTTD
Wall Stand MILLENNIUM: MILL-WBS
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

Radiographic System MULTIRAD:
MULTIRAD, Composed of:
Tube Stand MULTIRAD: MULT-FMTS
Table MULTIRAD: MULT-FWFTT
Wall Stand MULTIRAD: MULT-WBS
Power Supply: BRAKE BOX

MULTIRAD NET, Composed of:
Tube Stand MULTIRAD: MULT-FMTS
Elevating Table NET 4000: NET 4000-ST
Table MULTIRAD: MULT-FWFTTD
Wall Stand MULTIRAD: MULT-WBS
Wall Stand MILLENNIUM: MILL-WBS
Power Supply: BRAKE BOX
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

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

NOVAAT, 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

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Management System Certificate ES23/00000120,
continued



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

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

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
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

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
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

X-Ray Generator Console:

X Ray Generator Console: CTSC
(EMDN: Z11039006; Basic UDI-DI: 843604600CONSOLEM9)

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - ES/MAD/c300002079 - SUR 1.18 + CTC

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

Change in between this certificate and previous one: Addition to certificate scope of; Battery Portable X-Ray Unit, Capacitor Mobile X-Ray unit and models in Mobile-X Ray Generator: SPSB&SPB

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

