

Certificate ES19/85885

The quality management system of

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

C/ Pelaya, 9 Polígono Industrial Rio de Janeiro 28110 Algete (Madrid). Spain.
Facility number: F003910

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations SOR/98-282, Part 1

Japan: Japan PMD Act (as applicable), MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, manufacture and service of X-ray generators and X-ray systems (stationary, mobile, portable and monoblocks), X-ray tube starters and radiological positioners for use in X ray equipments.

This certificate is valid from Effective date 2024-07-19 until Expiry date 2027-07-19 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2019-05-08

Certified activities performed by additional sites are listed on subsequent pages.

L. Henderson

Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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Certificate ES19/85885, continued

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

SGS

MDSAP (ISO 13485:2016)

Issue 4

Campuses

C/ Pelaya, 9 Polígono Industrial Río de Janeiro 28110 Algete (Madrid). Spain.

C/ Pelaya, 13 Polígono Industrial Río de Janeiro 28110 Algete (Madrid). Spain

C/ Pelaya, 19 Polígono Industrial Río de Janeiro 28110 Algete (Madrid). Spain

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

C/ Navas, 6 Polígono Industrial Río de Janeiro 28110 Algete (Madrid). Spain

C/ Navas, 4 Polígono Industrial Río de Janeiro 28110 Algete (Madrid). Spain

C/ Navas, 2 Polígono Industrial Río de Janeiro 28110 Algete (Madrid). Spain

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



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