



Certificate Number ES19/85885

The management system of

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

Polígono Industrial Rio de Janeiro, C/ Pelaya, 9-13,
Algete, 28110 Madrid. Spain

Dun & Bradstreet D-U-N-S identification number : 51-094-8979

has been audited against the criteria stated below and found to conform to those criteria for the scope
contained in this certificate

MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from

Effective Date: 2019-05-08 until Expiry Date: 2022-05-07
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2021-07-19

Issue 1. Certified since 2019-05-08

Authorised by J Hall
Business Manager



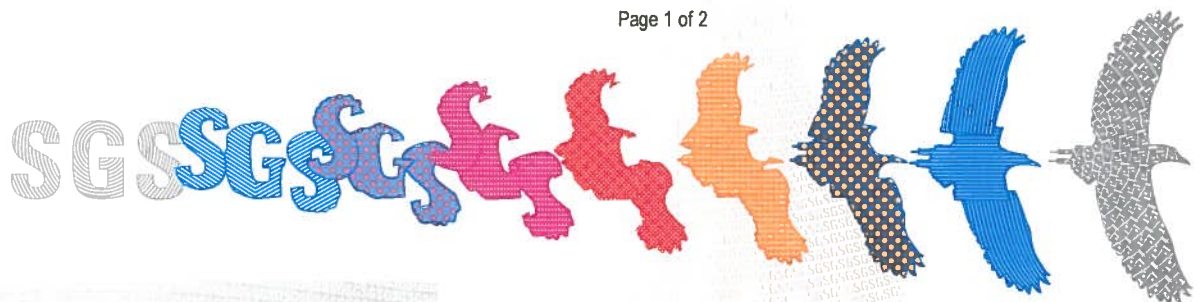
Jonathan M. Hall

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA,UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Certificate Number ES19/85885, continued



The management system of

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



Issue 1

Detailed scope

Design and manufacture 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.

Additional facilities

**Navas, 3, Poligono Industrial Rio de Janeiro,
Algete, 28110 MADRID. Spain**

**Rafael Pillado Mourelle, 6 Nave C-5, Poligono Industrial Rio de Janeiro,
Algete, 28110, MADRID. Spain**

