

Certificate ES97/9149

The management system of

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

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 20 July 2018 until 19 July 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 19 July 2021 Issue 21. Certified since 28 January 1997

This is a multi-site certification. Additional site details are listed on the subsequent page.

Authorised by



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Certificate ES97/9149, continued

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

ISO 13485:2016 EN ISO 13485:2016



Issue 21

Detailed scope

Design, manufacture, sales and technical support to customers of X-ray generators and X-ray systems (stationary, mobile, portable and monoblocks), X-ray tube starters, radiological positioners and ozone generators.

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

