EC Certificate Full Quality Assurance System: ES97/9864

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

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

This certificate is valid from 30 June 2019 until 19 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 July 2021
Issue 54. Certified since 20 May 1997

Certification is based on reports numbered ES/MAD 133585

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

Authorised by

Jonathan M. Hall

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

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

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 54

Detailed scope

Ozone Generator:
OM-302, OM302E, OM302IE, OM302IU, OM302IJ
OZONOBARIC P
OZONETTE

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

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

SEDECAL

DECLARACIÓN CE DE CONFORMIDAD CON EL MARCADO CE
(DIRECTIVA DE PRODUCTOS SANITARIOS 93/42/CEE ENMIENDA 2007/47/CE-REAL DECRETO 1591/2009)

EC DECLARATION OF CONFORMITY FOR CE MARKING

(FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICE DIRECTIVE 93/42/EEC & AMENDMENT 2007/47-SPANISH ROYAL DECREE 1591/2009)

Nosotros
We

SEDECAL, Sociedad Española de Electromedicina y Calidad, S.A.
C/Pelaya 9/13, Polígono Industrial Río de Janeiro, 28110 Algete (Madrid), España

Declaramos bajo nuestra responsabilidad que los productos Clase IIb:
Declare under our sole responsibility that the Products Class IIb:

Generador de Ozono: OZONETTE

Ozone generator: OZONETTE

están en conformidad con los Requisitos Esenciales que le son aplicables (Anexo I).
are in compliance with the Essential Requirements which apply to them (Annex I)

Esta conformidad está basada en los siguientes elementos:
This conformity is based on the following elements:

- La información contenida en el documento **"Archivos Técnicos F62_2A"** de los productos al que esta declaración hace referencia.
  *Information included in the document **"Technical Files F62_2A"** of the Product to which this declaration relates.*

- Certificado CE de aprobación del Sistema completo de Aseguramiento de la Calidad (Anexo II) emitido por el **Organismo Notificado Nº 0120,** SGS United Kingdom Ltd. Certificate No. ES97/9864.
  *CE certificate : approval of full of Quality Assurance System (Annex II) delivered by the **Notified Body No. 0120,** SGS United Kingdom Ltd., Certificate No. ES97/9864.*

Fecha (*Date*): 06 / 10 / 2015

Maria Luisa Gómez de Agüero Gómez
Director de Calidad y Reglamentación
Quality & Regulatory Manager

PS/DP/MST 679/2015-CERT.

Dª Mª Carmen Abad Luna, Jefe del Departamento de Productos Sanitarios de la Agencia Española de Medicamentos y Productos Sanitarios,

CERTIFICA:

Que la empresa SOCIEDAD ESPAÑOLA DE ELECTROMEDICINA Y CALIDAD S.A., (SEDECAL), con sede en la C/ PELAYA Nº 9, POLÍGONO INDUSTRIAL RÍO DE JANEIRO, 28110 ALGETE (MADRID), cuenta con licencia previa de funcionamiento como fabricante de productos sanitarios, en aplicación de la legislación española, correspondiéndole el Nº 28-PS.

Que entre los productos fabricados, se encuentra el siguiente, que cuenta con marcado CE, en aplicación de la Directiva 93/42/CEE, relativa a los productos sanitarios, lo que permite su comercialización en España y en el resto de los países de la Unión Europea, no existiendo trabas para su exportación.

- **Generador de Ozono: OZONETTE**

Y para que conste y surta los efectos oportunos ante QUIEN CORRESPONDA, lo firmo en Madrid a nueve de diciembre de dos mil quince.

agencia española de medicamentos y productos sanitarios
Departamento de Productos Sanitarios

CORREO ELECTRONICO

sgps@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 52 61
FAX: 91 822 52 89

SEDECAL
Sociedad Española de Electromedicina y Calidad S.A.

CERTIFICATION OF CONFORMITY

The RoHS Directive 2011/65/EU restricts the use of certain substances including lead, mercury, cadmium, hexavalent chromium and halogenated flame retardants PBB and PBDE in electrical and electronic equipment.

Hereby SEDECAL declares that A10066-01 OZONETTE with all its containing parts and components contains less than the RoHS limits stated below for the six restricted substances and is in conformity with the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

This declaration is based on analysis, vendor supplied analysis or material certifications, supplier declarations in any means, and/or lab test results of the component raw materials used in the manufacturing process of SEDECAL products.

This declaration of conformity is issued under the sole responsibility of the manufacturer or installer.

Restricted substances referred to in Annex II in the RoHS Directive 2011/65/EU and maximum concentration values tolerated by weight in homogeneous materials are:

- Lead (0,1%)
- Mercury (0,1%)
- Cadmium (0,01%)
- Hexavalent chromium (0,1%)
- Polybrominated biphenyls (PBB) (0,1%)
- Polybrominated diphenylethers(PBDE) (0,1%)

Algete, 7th March 2016

SEDECAL
Sociedad Española de Electromedicina y Calidad S.A.
N.I.F. A80-766496
Algete (Madrid) - España

Maria Luisa Gomez de Agüero
Quality & Regulatory Manager

SEDECAL
Sociedad Española Electromedicina y Calidad
Registration number : NIF A-80.766.496
Address:
C/. Pelaya, 9 - 13
Pol. Ind. "Río de Janeiro"
28110 Algete (Madrid)
Tel: (+34) 916 280 544
Fax: (+34) 902 190 385
Email: guest@sedecal.com