

EC Certificate Full Quality Assurance System: Certificate ES19/86925

The management system of

S.E. Carburos Metálicos, S.A.

Av. de la Fama, 1 08940 Cornellà del Llobregat, Barcelona. 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 16 December 2019 until 26 February 2023 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 15 May 2012 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered ES/MAD 163566

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

Authorised by

Altang

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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Certificate ES19/86925 continued

S.E. Carburos Metálicos, S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Medical Gas Pipeline System including Vacuum and AGSS in hospitals and clinics for medical use.

Sistema de distribución de gases medicinales, incluyendo vacío y SEGA en hospitales y clínicas para uso médico.

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

Parque Empresarial Vía Norte (Edificio 3, Planta baja), C/ Quintanavides, 17, 28050 Madrid. Spain

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