

EU Quality Management System Certificate ES24/00000039

The management system of

S.E. Carbueros Metálicos, S.A.

Av. de la Fama, 1, 08940 Cornellà de Llobregat. Barcelona. Spain

SRN Number: ES-MF-000003117

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

Class IIb device - MDA0316; EMDN Z120309; Basic UDI-DI 8420219MGPS3A

Pipeline Distribution System for compressed medical gases, vacuum and Anaesthetic Gas Scavenging System (AGSS).

Sistema de Distribución para gases medicinales comprimidos, vacío y Sistema de Extracción de Gases Anestésicos (SEGA)

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation:

N/A

Certification is based on following reports: ES/MAD/c300002046 - S2A 1.1

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 09 January 2024 until 09 January 2029 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 July 2029

Issue 1. Certified since 09 January 2024

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



Authorised by

Virginie Siloret

Global Medical Device Certification
Manager

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Issue 1
Sites
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