



# EC CERTIFICATE

## Full Quality Assurance System

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Certificate No.:

14538-2019-CE-IBE-NA rev.1.0

Project No.:

PRJC-546166-2016-PRC-ESP

Valid Until:

03 May 2024

This is to certify that the quality system of:

### **SE CARBUROS METALICOS, S.A.**

Avda.de la Fama, 108940 Cornellá de Llobregat, BarcelonaSpain

For design, production and final product inspection/testing of:

**MANUFACTURE, STORAGE AND DISTRIBUTION OF MEDICAL GASES  
IN LIQUID OR GAS IN CRYOGENIC CONTAINERS AND MOBILE  
CYLINDERS.**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II  
excluding section 4 of Council Directive 93/42/EEC on Medical  
Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:

Høvik, 24 May 2021

For the issuing office:

**Notified Body 2460  
DNV Product Assurance AS**



**Sholeh Gheissar**  
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-i1-MDD-f2, rev.0

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	03-05-2019
1.0	Updated ( <b>in bold</b> ) the Argon classification from Class IIa to Class IIb	24-05-2021

Products covered by this Certificate:

Product Description	Product Name	Class
MD 1105 Gases for ophthalmical purposes	SF6 Sulphur Hexafluoride in cylinders of 0.5l to 50l	IIb
	C3F8 Propane Octafluoride in cylinders of 0.5l to 50l	
MD 1104 Gas for surgical cryotherapy and insufflations	CO2 in cylinders of 2l to 50l	IIb
MD 1104 Gases for cryosurgery	N2 in mobile tank of 5l to 600l	IIa
	N2O in cylinders of 2l to 50l	
MD 1104 Gas for electrocoagulation	Ar in cylinders of 0.5l to 50l	IIb
MD 1110 Gases for in vitro fertilisation	Mixtures of CO2/O2/N2 in cylinders 0.5l to 50l	IIa
MD 0102 Gases for human cell biology	Mixtures of CO2/H2/N2/O2 in cylinders of 0.5l to 50l	IIa

The complete list of devices is filed with the Notified Body

## Sites covered by this certificate

Site Name	Address
SE CARBUROS METALICOS, S.A.	Polígon Nordest C-35 Km.59, 08470 Sant Celoni, Barcelona, Spain
SE CARBUROS METALICOS, S.A.	Ctra. de Toledo, 7, 28300 Aranjuez, Madrid, Spain
SE CARBUROS METALICOS, S.A.	P.I. Ca n'Estella, C/ Doctor Feming, 29, 08635 Sant Esteve Sesrovires, Barcelona, Spain

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate