

EC Certificate

Production Quality Assurance System

Certificate No.:
10119-2017-CE-IBE-NA-PS

Project No.:
PRJC-546034-2016-PRC-ESP

Valid until:
12 April 2022

This is to certify that the quality system of:

SE CARBUROS METALICOS, S.A.

Avda.de la Fama, 1, 08940 Cornellà de Llobregat (Barcelona), Spain

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

MD1104 Active surgical devices

Has been assessed with respect to:

**The conformity assessment procedure described in Article 11.2.b
and Annex V (Module D1) 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, 12 April 2017



For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus
Certification Manager

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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



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Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0	Original Certificate	2017-04-12

Products covered by this Certificate:

Product Description	Product Name	Class
LIQUID NITROGEN IN BULK FOR CRYOPRESERVATION AND CRYOTHERAPY	Bulk liquid nitrogen	Ila

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

SE CARBUROS METALICOS, S.A.
Avda.de la Fama, 1, 08940 Cornellà de Llobregat (Barcelona), Spain

S.E. Carburos Metálicos, S.A.
Ronda Valdecarrizo, 49, 28760 Tres Cantos

S.E. Carburos Metálicos, S.A.
Polig. Industrial El Morell, Apartado 343760 El Morell

S.E. Carburos Metálicos, S.A.
Urbanizacion Ind. Salinetas, 35219 Telde

EU Representative NA

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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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate