

# EC CERTIFICATION

## QUALITY MANAGEMENT SYSTEM CERTIFICATE Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

### S.E. Carbueros Metálicos, S.A.

Avda de la Fama, 1, 08940 Cornellà de Llobregat, Barcelona, Spain

Manufacturer SRN: ES-MF-000003117

#### Scope:

- Medical gas for cryopreservation and cryotherapy
- Argon for clinical/therapeutic applications

**Certificate Number:**

28620184382

**Revision:**

00

**Initial Certification Date:**

20 August 2024

**Certificate Decision Date:**

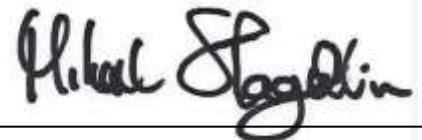
20 August 2024

**Certificate Issue Date:**

20 August 2024

**Certificate Expiry Date:**

7 July 2029



Mikael Hagelin  
Certification Authority, MDR  
Intertek Medical Notified Body AB,  
Torshamnsgatan 43,  
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



**PRODUCT LIST FOR CERTIFICATE**

*See attached product list*

**EXAMINATION AND TESTS PERFORMED**

Technical Assessment Report Reference	TD00366-01 S.E. Carbueros Metálicos, S.A. LIN Mobile Cryogenic Vessels for Cryopreservation
	TD00366-02 S.E. Carbueros Metálicos, S.A. Argon in cylinders Gas for electrocoagulation
Audit Report Reference	Stage 1 audit ACTY-2023-120234
	Stage 2 audit ACTY-2023-120239
	Special visit audit ACTY-2024-222363

**CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE**

None
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

**Certificate Number:**  
28620184382

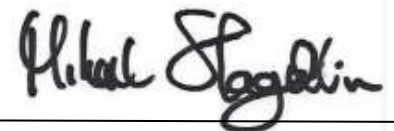
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## PRODUCT LIST FOR CERTIFICATE

**Issued to:** S.E. Carburos Metálicos, S.A.  
**Certificate number:** 28620184382  
**Certificate valid from:** 0024-08-20

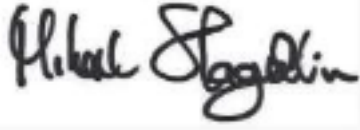
**Product List Issue Date:**  
20 August 2024

Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
<b>Argon for clinical/therapeutic applications</b>			
<i>Basic UDI-DI: 8420219ARGONTF</i>			
Argon in cylinders Gas for electrocoagulation	Class IIb V0905	Argon is used in a non-contact form of electro-cauterization which refers to the application of electrically-induced thermal energy to coagulate tissue. It is used in a plasma coagulator device that uses high-frequency mono-polar current that is conducted through ionized argon gas (argon plasma) to the target tissue.	2024-08-20
<b>Medical gas for cryopreservation and cryotherapy</b>			
<i>Basic UDI-DI: 8420219CO2CRYOKV</i>			
CO2 Carbon Dioxide in cylinders Gases for surgical cryotherapy	Class IIa V0901		2024-08-20
<i>Basic UDI-DI: 8420219LINBULKWA</i>			
LIN Bulk for Cryopreservation	Class IIa V0902		2024-08-20
LIN Bulk for Cryotherapy	Class IIa V0902		2024-08-20
<i>Basic UDI-DI: 8420219LINCERYOXH</i>			
LIN Mobile Cryogenic Vessels for Cryopreservation	Class IIa V0902		2024-08-20
LIN Mobile Cryogenic Vessels for Cryotherapy	Class IIa V0902		2024-08-20
<i>Basic UDI-DI: 8420219N2OCRYOPY</i>			
N2O Nitrous Oxide in cylinders Gases for surgical cryotherapy	Class IIa V0904		2024-08-20

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
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*Certificate number: 28620184382*

*Product list issue date: 20 August 2024*

