EC CERTIFICATION

QUALITY ASSURANCE CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex XI Part A

We hereby declare that a conformity assessment based on a production quality assurance system and technical documentation (excluding type-examination) has been carried out following the requirements of EU Regulation 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.

Certificate Number:
28620118892-01

Initial Certification Date:
1 November 2021

Certificate Issue Date:
3 December 2021

Certificate Expiry Date:
31 October 2026

Air Products PLC

Millennium Gate 2 Westmere Drive, Crewe, CW1 6AP, United Kingdom

Manufacturer SRN: GB-MF-000017093

Authorized Representative

Air Products France

45 Avenue Victor Hugo, Bâtiment 270, Parc des Portes de Paris, 93 300 Aubervilliers

Scope:

Medical gas for cryopreservation and cryotherapy

Brian Mather
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	**TD00008-01 Air Products - Liquid Nitrogen**
Audit Report Reference	**Stage 1 audit ACTY-2020-433196**
	Stage 2 audit ACTY-2020-433197

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

Certificate Number:
28620118892-01

Initial Certification Date:
1 November 2021

Certificate Issue Date:
3 December 2021

Certificate Expiry Date:
31 October 2026

Brian Mather
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.

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620118892	1 November 2021	SRN added according to Change Note CN00008-01. Exp. Date extended to full 5 years.

MDR – Decision Report

Certificate No:	28620118892-01
Date:	3 December 2021
Handled by:	Carmina Luz Pecson
E-mail:	IMNB@intertek.com

Air Products PLC
2 Millennium Gate
Westmere Drive
Crewe
CW1 6AP, UK

Purpose	Assessment to issue an updated certificate due to addition of SRN number according to the Medical Device Regulation 2017/745, Annex XI.
Activity	Change Notice Form to add SRN number missing on initial certificate. Expiry date extended to full 5 years.
Scope of assessment	Medical gas for cryopreservation and cryotherapy Liquid Nitrogen Class IIa
Result	The addition of SRN number has been accepted. Revised MDR Certificate and Product List will be issued to reflect the addition of SRN. Expiry date extended to full 5 years.
Certificate Valid from	3 December 2021
Conclusions/Decision	Referring to the above a Certificate of Conformance with the Device Regulation 2017/745, Annex XI will be issued. The Certificate is valid for products specified in the “MDR – Product List”.
Follow-up	Follow-up assessments are going to be performed as detailed in the sampling plan.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden (imnb@intertek.com).
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

MDR – Decision Report

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority

PRODUCT LIST FOR CERTIFICATE

Issued to: Air Products PLC

Certificate number: 28620118892-01

Certificate valid from: 2021-12-03

Product List Issue Date:
03 December 2021

Product	Classification and EMDN	Intended use[1]	Date Added
Medical gas for cryopreservation and cryotherapy			
Basic UDI-DI: not yet provided			
Medical Device LIN (MLN) for Cryopreservation - Liquid Nitrogen	Class IIa		2021-11-01
Medical Device LIN (MLN) for Cryotherapy - Liquid Nitrogen	Class IIa		2021-11-01

Brian Mather
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.

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.