DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 75713-2010-CE-FRA-DNV 2.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Air Products Management bvba

Brussels, Belgium

for design, production and final product inspection/testing of
Gases for electro coagulations, Gases for human cells biology
Gases for ophthalmic purposes, Gases for in vitro fecondation
Gases for coeliosurgery, Gases for cryosurgery
Gases for human medical biology

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 06 November 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Alexey Shiryaev
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
04 May 2019

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

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 (70428-2010-CE-FRA-NA and 51900-2009-CE-FRA-NA Rev. 1.0)	2010-09-22
1	**Recertification**	**2014-11-06**

Products covered by this Certificate

Product Description	Product	Class
Argon in cylinders of 0,5l to 50l water volume	Gases for electrocoagulation	IIa
Mixtures of CO2/H2/N2/O2 in cylinders of 0,5l to 50 l water volume	Gases for human cell biology	IIa
SF6 Sulphur Hexafluoride, C2F6 Ethane Hexafluoride, C3F8 Propane Octafluoride, in cylinders of 0,5l to 50l water volume	Gases for ophthalmological purposes	IIb
FIV	Gases for in vitro fertilisation	IIa
Carbon Dioxide CO2 in cylinders of 0.6 l to 50l water volume	Gases for laparoscopic surgery	IIa
Carbon dioxide CO2, Nitrous oxide N2O, in cylinders of 2l to 50l of water volume	Gases for cryosurgery	IIa
Nitrogen N2, tank of 5l to 600l water volume	Gases for cryosurgery	IIa
Nitrous oxide N2O in cylinders of 2l to 20l water volume	Gases for cryosurgery	IIa
Carbon dioxide CO2 in cylinders of 2l to 50l water volume	Gases for human cell biology	IIa

Site Name	Address
Air Products Management bvba	Waversesteenweg 1789, B-1160 Brussel, Belgium
S.E. Carburos Metalicos, S.A.	Crta de Toledo, E-28700, ARANJUEZ, Spain
Air Products SAS	Zi de l'Epinoy, 59175 Lille TEMPLEMARS, France
S.E. Carburos Metalicos, S.A.	Poligono Nord Este C-35, km 59,2 08470 SANT CELONI, 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 local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE