

# Liquid Nitrogen: Medical Device Regulation (MDR) Certified



# For users of Cryopreservation and Cryotherapy, find out if you need to be using MDR liquid nitrogen.

The recent introduction of the more stringent MDR certification, which replaced the Medical Device Directive (MDD) requires anyone working in cryopreservation or cryotherapy who use liquid nitrogen to ensure that it is MDR certified.

Air Products is currently the only industrial gas company manufacturing liquid nitrogen in the UK that complies to the new medical Device Regulation.

## Do I need MDR liquid nitrogen?

It depends on your application. If it involves the storage of human tissue samples the chances are that you do.

This includes any applications that use liquid nitrogen for preserving blood and bone marrow cells, sperm, ova, early embryos, and, in the microbiology laboratory, a variety of microorganisms (bacteria, fungi, etc) Another application that requires MDR liquid nitrogen is cryotherapy, which refers to the focal application of extreme cold for the *in-situ* destruction of abnormal or diseased tissue.

## What does MDR Device liquid nitrogen actually mean?

Liquid nitrogen that could come into contact with life science samples through cryogenic storage or cryotherapy is classified as a class IIa medical device, compliance with the MDR means that we as the manufacturers need to ensure that:

- The device has been correctly classified against the new risk classification criteria (Annex VIII of the MDR and IVDR)
- General safety and performance requirements are met, including for labelling, and technical documentation and quality management systems (Annex I of the MDR and IVDR)
- Increased requirements for clinical evidence are met (Annex XIV of the MDR and IVDR)
- Manufacturers have a person responsible for regulatory compliance in place (Article 15 of the MDR and IVDR)

## I have heard of the Medical Device Directive (MDD) but what is the Medical Device Regulation (MDR)?

The MDR replaced the MDD in May 2021. The MDR is substantially more comprehensive and detailed compared to the MDD. The MDR document is four times longer than the MDD and puts more emphasis on product safety. Nothing from within the MDD has been removed, rather the MDR has only added new requirements.

Air Products have completed months of work to ensure that liquid nitrogen manufactured and supplied within the UK complies with the new more comprehensive Medical Device Regulation.

## I need MDR liquid nitrogen, how can I get it?

Air Products is currently the only industrial gas company manufacturing liquid nitrogen in the UK that complies with the new MDR, contact us today to discuss your requirements.

The latest version of the MDR Quality assurance Certificate is available to download from [www.airproducts.expert/uk/biomedical](http://www.airproducts.expert/uk/biomedical)

# Cryopreservation

The use of liquid nitrogen for preserving blood and bone marrow cells, sperm, ova, early embryos, and, in the microbiology laboratory, a variety of microorganisms (bacteria, fungi, etc).

## Air Products is a complete provider of cryopreservation solutions:

By partnering with MVE BioMedical, world leaders in cryogenic storage vessels, we are uniquely placed to offer all aspects of cryogenic sample storage, from all sizes of cryo-storage vessels to liquid nitrogen supply. Ensuring you have the safest and most economical storage solution for your samples. Air Products is the preferred distributor in the UK & Ireland for the MVE range of Cryogenic equipment.

- Supply of MDR certified liquid nitrogen
- Large selection of Cryogenic freezers;
  - Liquid nitrogen
  - Nitrogen vapour
  - Variable temperature
  - Auto or manual fill
- External cryogen bulk tanks or smaller volume via the **Cryoease®** microbulk storage solution
- Dewars for storage or transportation of liquid nitrogen
- Cryogenic shippers, with QWick charge and hold times of up to 30 days
- Cryo-room design service

# Air Products is your complete cryogenic supplier, growing with your storage needs, every step of the way

## Small scale

Dewar storage, liquid gas deliveries as required.



Liquid & cylinder delivery



Storage dewars

## Medium scale

Cryogenic freezer with dry sample storage, liquid gas bulk container refilled on site.



Microbulk liquid deliver



Microbulk storage



Cryogenic freezers

## Large scale

Complete project management, remote monitoring of onsite liquid gas levels, pipeline to network of cryogenic storage freezers.



Bulk liquid delivery



Bulk storage



Insulated pipeline



Project management



Dry vapour shipping





# Cryotherapy

The focal application of extreme cold for the in-situ destruction of abnormal or diseased tissue.

Cryotherapy, sometimes known as cryosurgery is a type of surgery that uses the extreme cold of liquid nitrogen to destroy abnormal tissue such as warts, moles, skin tags and other skin lesions. The high cure rate, combined with excellent cosmetic results and ease of operation, makes liquid nitrogen cryosurgery the most versatile cryosurgical treatment, available at a very low cost per treatment.

## As part of our cryotherapy service we supply

- All equipment required for storing and dispensing liquid nitrogen. Our modest sized Dewars (for storage of liquid nitrogen) are available in 30 or 50L capacity
- Delivery of MDR certified liquid nitrogen to site, choose from 4, 8 or 16 deliveries per year to suit your requirements
- Cryosurgical specific equipment, including spray applicator and contact probes



Contact us for more information or visit our website where you can use our interactive delivery selector tool, quickly and easily identify the right size Dewar and find the delivery schedule to suit your requirements.

[www.airproducts.expert/uk/dewar-service](http://www.airproducts.expert/uk/dewar-service)

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