

Classification of Medical Device Gases According to European Medical Device Regulations

Introduction

This Technical Bulletin has been prepared by specialists from EIGA Member Companies and is their interpretation and opinion of how medical gases meeting the definition of medical devices should be classified according to specific regulations or legislation. This Technical Bulletin is not a legally binding interpretation and for this reference needs to be made to the appropriate authority.

Carbon dioxide (CO₂), nitrogen, argon as well as other gases depending on their purpose in medical applications need to be defined as medical devices. A classification based on the risk is defining the required procedure for CE marking of the medical device, see [1] and [2].

With the introduction of 2017/745/EU also known as Medical Device Regulation, (MDR) [2] some uncertainties on classification due to the new classification rule 21 for substance-based medical devices occurred.

Scope

Classification of carbon dioxide, nitrogen and argon as medical devices according MDR classification rules. Further gases could be included in updates.

Purpose

This Technical Bulletin puts forward an EIGA position that provides guidance for the classification of medical device gases to establish a harmonised approach and to avoid different interpretations of rules and risk classes across the different EU member states.

Summary

Based on the information detailed in the sections below, the proposed classification for the different applications of nitrogen (N₂), carbon dioxide and argon according to the Medical Device Regulation (MDR) 2017/745/EU are the following:

Product	Intended Use	Classification MDR
Nitrogen (N ₂) – Liquid	Cryopreservation, cryotherapy (including cryosurgery)	Ila
Nitrogen (N ₂) – Gaseous	Source of supply for incubators	Not a MD
Carbon dioxide (CO ₂) – Gaseous	Insufflation during minimal invasive surgery and colonoscopy	Ila
Carbon dioxide (CO ₂) – Gaseous	Source of supply for incubators	Not a MD
Carbon dioxide (CO ₂) – Liquid	Cryotherapy (including cryosurgery)	Ila
Pure Carbon dioxide (CO ₂) or its Mixtures with O ₂ and N ₂	In vitro buffer for Human cells culture, including IVF	I
Argon	Plasma coagulation	Ila

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Definitions

Definitions from Medical Device Regulation (MDR) 2017/745/EU

MDR
Transient means normally intended for continuous use for less than 60 minutes.
Short term means normally intended for continuous use for between 60 minutes and 30 days.
Long term means normally intended for continuous use for more than 30 days
Body orifice means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.
Invasive device means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body
Surgically invasive device means: (a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and (b) a device which produces penetration other than through a body orifice.
Implantable device means any device, including those that are partially or wholly absorbed, which is intended: - to be totally introduced into the human body, or - to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device
Active medical device 'active device' means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device
Active therapeutic device means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.
Active device intended for diagnosis and monitoring means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
Injured skin or mucous membrane means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

Definitions from MDCG 2021-24

Systemic absorption: The process by which substances or their metabolites enter the body (e.g. by crossing mucous membranes) and are distributed into the body via the blood and/or lymphatic system.
Wholly or mainly absorbed: The term 'absorption' in the context of implantable devices refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. It does not apply to those substances that are excreted without modification from the body, e.g. insufflation gases for the abdominal cavity or laparoscopic and endoscopic procedures.
Local dispersion: The condition by which substances remain in a specific site without being distributed into the body via the blood and/or lymphatic system.

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EUROPEAN INDUSTRIAL GASES ASSOCIATION AISBL
AVENUE DE L'ASTRONOMIE 30 • B-1210 BRUSSELS
PHONE +32 2 217 70 98 • E-mail: info@eiga.eu www.eiga.eu

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Other definitions

Cryotherapy: A generic term that is used to describe therapies which are based on the use of low temperatures and includes cryosurgery as specific application.

Conventions

The portions of text of the classification rules that apply to the medical device gas under examination are underlined.

The rules or parts of rules which are not applicable but need an explanation or a rationale for that are shown.

The rules or parts of rules whose non-applicability is obvious are not shown.

Nitrogen (N₂)

Liquid nitrogen for cryopreservation of human samples for medical purpose

When liquid nitrogen is used for preservation of cells and tissues of human origin, intended to be re-implanted or re-used in the human body, it shall be considered as a medical device, even if direct contact with biological material does not occur.

MDR
Rule 2 <i>All non-invasive devices intended for channelling or storing blood, body liquids, <u>cells or tissues</u>, liquids or gases <u>for the purpose of eventual</u> infusion, administration or <u>introduction into the body</u> are classified as class <u>Ila</u>:</i> – if they may be connected to a class <u>Ila</u> , class <u>Ilb</u> or class <u>III</u> active device; or – <i>if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or <u>body cells and tissues</u>, except for blood bags; blood bags are classified as class <u>Ilb</u>.</i> <i>In all other cases, such devices are classified as class <u>I</u>.</i>
Conclusion: <u>Ila</u>

Liquid nitrogen for cryotherapy

LIN used as a source of cold for a cryoprobe. There is no contact of LIN with the tissue .

MDR
Rule 9 <i>All active therapeutic devices intended to administer or exchange energy are classified as class <u>Ila</u> unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class <u>Ilb</u>.</i>
Comments The “potentially hazardous way” is not retained because the application is made through a device that control the energy. Liquid nitrogen is only the source of cold
Conclusion: <u>Ila</u>

Liquid nitrogen for topical cryotherapy

In this use, LIN is applied directly on the tissue, for example in dermatology.

MDR
Rule 4 <i>All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:</i>

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AVENUE DE L'ASTRONOMIE 30 • B-1210 BRUSSELS

PHONE +32 2 217 70 98 • E-mail: info@eiga.be • www.eiga.eu