

Medical Gas Pipeline Systems: Purpose (Channelling versus Administration) and Applicable MDR Requirements

Introduction

Medical Device Regulation (EU) 2017/745 (MDR [1]) has introduced a new categorisation of medical devices, implying specific requirements, such as “class IIb active devices intended to administer and/or remove a medicinal product” (e.g. in Art. 54 MDR).

A Medical Gas Pipeline System (MGPS) is a singular medical device, and this type of equipment has been put into service in several countries under the Medical Device Directive 93/42/EEC (MDD [2]). However, the conformity assessment and classification have not been harmonised across EU Member States.

With the introduction of the MDR, the requirements applying to the MGPS need to be appropriately assessed because of potential implications.

Definition of Medical gas pipeline system (MGPS):

Complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required. [source: [ISO 7396-1:2016](#) [3]]

Scope

Medical gas pipeline system for distributing medicinal gases or medical device gases or vacuum.

Purpose

Clarify the concept of administration of medicinal products, so that the classification can be correctly applied and the associated requirements can be fulfilled.

Evaluate the corresponding implications for medical gas pipeline systems (MGPS).

Mainly, the questions are whether the MGPS:

1. Should be considered as active device (MDR, art.2(4)), and if so,
 - a. as *active therapeutic devices intended to administer or exchange energy* (MDR, Annex VIII, Rule 9, 1st paragraph);
 - b. as active devices intended to administer and/or remove a medicinal product (MDR, Annex VIII, Rule 12 & MDR Art. 54);
 - c. as active devices intended to control or monitor the performance of active therapeutic class IIb devices (MDR, Annex VIII, Rule 9, 2nd paragraph);
2. Should the MGPS be considered as *intended for channelling gases for the purpose of eventual infusion, administration or introduction into the body* (MDR, Annex VIII, Rule 2);

since no other rules apply under MDR.

Concept of active devices

Article 2 of MDR defines the 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.”

Therefore, considering that the MGPS is used to manage sources of gases that are pressurised it can be considered as an active device.

Concept of administration of medicinal products

MDR does not define the concept of administration of medicinal products, nonetheless:

- Rule 2 introduces the concept of channelling or storing gases for the purpose of eventual administration or introduction into the body, that applies clearly to a MGPS.
- Rule 12 introduces the concept of administering medicinal products to or from the body.

Therefore, channelling and administering can be considered as two different actions.

Since “administration” (of a dose of medicinal product) is not defined in:

- the Medical Device Directive,
- in European Medicines Agency [EMA-Glossary](#) (at the date of publication),
- European Directorate for the Quality of Medicines,
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,
- Medical Device Coordination Group guidelines (at the date of publication).

another source for definition should be found.

Some definitions are given in ISO standards, in GHTF (Global Harmonisation Taskforce), in NCI (US National Cancer Institute) and in NIH (US National Institute of Health). Despite being different from each other, their common interpretation is that **administration** is considered as **the act of giving a prescribed dosage of a medicinal product to a patient** (further explanations in annex I).

A MGPS only channels gas, which is stored in gas packages, up to the outlet point at a known pressure, **but does not control the amount of gas** which is administered to the patient from the terminal outlet. This aspect is controlled by the administration device, such as a flowmeter or a ventilator, which are connected but not part of the MGPS.

In [MDCG 2021-24](#) [4] “Guidance on Classification of Medical Devices”, in the section concerning Rule 12, all the examples given are clearly devices intended to supply a defined dose of medicinal product to single patients, and doesn't mention the MGPS.

Therefore, the MGPS shall not be considered as a device intended to administer medicinal products.

Assessment of the MDR classification rules

MDR Rule 2:

All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

- *if they may be connected to a class IIa, class IIb or class III active device; or*
- *if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.*

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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.be www.eiga.be



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