TECHNICAL BULLETIN

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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.

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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.*

In all other cases, such devices are classified as class I.

Considering that MGPS are:

- non-invasive,
- intended for channelling of gases for the purpose of eventual administration or introduction into the body
- connected to class IIa active devices (example: flowmeters) or class IIb active devices (example: ventilators), via terminal outlet,
- not intended for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues.

this rule applies and results in class IIa.

MDR Rule 9:

All active therapeutic devices intended to administer or exchange energy are classified as class IIa 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 IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

As the MGPS provides the gas at a fixed pressure to all terminal units, its only intended purpose is to provide sufficient gas to the active connected medical devices which independently control the therapeutic use of the gas for each patient.

Therefore, the MGPS is not

- an active therapeutic device,
- intended to control, monitor or directly influence the performance of an active therapeutic device (MGPS supplies gases at a fixed pressure to all of its terminal outlets, irrespective of the connected devices),
- intended to emit ionizing radiation,
- directly influencing the performance of active implantable devices,

Rule 9 does not apply.

MDR Rule 12:

All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

The MGPS is an active device supplying the medicinal product to the terminal outlets where the administration devices (e.g. flowmeters) will be connected to administer the gas to the individual patient according to the prescription. Therefore, the MGPS is not intended to administer medicinal products or other substances itself and, as a consequence, this rule does not apply (see annex II of this document for more details on the concept of administration).

Rule 12 does not apply to the MGPS;

Consequently, the requirements of the MDR concerning class IIb active devices intended to administer medicinal products, such as Art. 54 “Clinical evaluation consultation procedure for certain class III and class IIb devices” do not apply;

MDR Rule 13:

All other active devices are classified as Class I.

Rule 13 does apply to MGPS.

All the other rules have been evaluated and are considered not applicable.

Conclusion

Since both Rule 2 and Rule 13 apply, MGPS is classified as class IIa.

Furthermore, the additional requirements for the clinical evaluation according to MDR Article 54 do not apply.

References

[1]	Regulation (EU) 2017/745	Medical Device Regulation
[2]	Directive 93/42/EEC	Medical Device Directive
[3]	ISO 7396-1	Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum
[4]	MDCG 2021-24	Guidance on classification of medical devices
[5]	ISO/TS 19256	Health informatics — Requirements for medicinal product dictionary systems for health care

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Annex I: Definitions of "Administration" from various relevant sources

Administration:
act of (self-)administering a (prescribed) medicinal product to the patient, using an administration method, and via a defined route, and recording that the act has actually happened at a particular date and time.
[source: ISO/TS 19256:2016 [5]

In medicine, the act of giving a treatment, such as a drug, to a patient. It can also refer to the way it is given, the dose, or how often it is given.

[source: National Cancer Institute]

The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling."

[source: International Medical Device Regulators Forum Principles of Medical Devices Classification: Page 15: "Note"]

Administration device:
equipment intended for correct administration of the Medicinal Product.
Example: Applicator, needle, oral syringe.
Note 1 to entry: An administration device can be an integral part of an immediate container or a closure.
[source: ISO/TS 19256:2016 [5]

Administration method:
general method by which a pharmaceutical product is intended to be administered to the patient.
Example: Application, inhalation, injection.
Note 1 to entry: The administration method is a general term that is used to group related pharmaceutical dose form concepts, and is not intended to describe a precise method or route of administration.
[source: ISO/TS 19256:2016 [5]

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