TECHNICAL BULLETIN

Prepared by WG-15 TB 47/23 – January 2023

Potential Impact of Medical Device Regulation Transition Process on Product Availability

Introduction

The medical device regulation 2017/745 EU (MDR) is now fully in force and the transition period will end in May 2024.
In its recently published document MDCG 2022-14, the Medical Device Coordination Group (MDCG) has re-affirmed that the transition period will **not** be extended, although recognising that:

> "*significant and urgent challenges remain in ensuring sufficient capacity of notified bodies and readiness of manufacturers in order to allow medical devices and in vitro diagnostic medical devices to be certified in accordance with the MDR and the IVDR within the transition periods*".

Regulatory issue

With the reapproval process by the Notified Bodies expected to take at least one year, the time for preparation of the documentation is very limited.

Despite the MDCG suggested actions for streamlining the certification process, there is a risk that MDR CE certificates are not issued in time, due to the number of expiring certificates, the limited capacity of Notified Bodies and the long approval process, leading to product shortages.

In the event the MDR CE certificate is not issued before the expiry date of the current certificate or at the latest the 26th May 2024, a derogation might be requested by the Manufacturer from the Competent Authority, but it might only be granted in **very limited cases** where at least:

- it can be demonstrated that the use of the device concerned is in the interest of public health, patient safety or patient health, and
- the application for the conformity assessment procedure has been submitted within a suitable timeframe that should have allowed the Notified Body to review the submitted documentation and issue the certificate by the due date.

Impact on product availability

Due to this situation, the medical gas sector may be impacted by shortages of medical devices that are:

1. manufactured by the EIGA member companies such as:

- Carbon dioxide for insufflation and cryotherapy
- Liquid nitrogen for cryotherapy and cryopreservation
- Argon for plasma coagulation
- Nitrous oxide for cryotherapy
- Ophthalmic gases
- Air and nitrogen for driving tools
- Liquid air for cryotherapy
- Gas mixtures for medical applications

***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

- Medical gas pipeline systems
- Vacuum pipeline systems
- Anaesthetic gas scavenging systems
- Cryogenic lines for cryobanks

2. used for administering medicinal and medical device gases supplied by EIGA member companies, such as:

- Valves with integrated pressure regulators
- Pressure Regulators
- Flow meters
- Gas mixers
- Dosing systems
- Demand valves
- Single patient use interfaces (e.g. tubing, masks…)
- Cryogenic vessels for oxygen
- Cryogenic vessels for cryopreservation
- Components of the pipelines (e.g. Terminal units, Line pressure regulators…)

Recommendations

For medical devices directly manufactured by EIGA member companies, EIGA recommends to each company to apply as soon as possible for the conformity assessment procedure under MDR with their Notified Body to allow the completion of the assessment before May 2024 and to be in the position to request a derogation in case of delay by the Notified Body.

For medical devices purchased by EIGA member companies (e.g. used for administering medical gases), EIGA recommends each member company to check with their suppliers if they are willing to apply for the conformity assessment procedure of their devices and in such cases to strongly encourage them to do this as soon as possible.

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