TECHNICAL BULLETIN

Prepared by WG-15 TB 31/19 – September 2019

MDR Implementation – Consequences for Notified Bodies and Impact on Medical Device Industry

EIGA has prepared this Technical Bulletin to raise their concerns about the implementation of the new Medical Devices Regulation (MDR) and consequences for all parties involved including Notified Bodies, Medical Device Industry and users.

Medical Device manufacturers are strongly recommended to check the progress of their current Notified Body in becoming notified under MDR and be prepared to identify an alternative Notified Body in the event of a delay in becoming notified under the new regulation.

Introduction

This Technical Bulletin has been prepared by EIGA Members and is their interpretation and opinion of potential consequences resulting from the notification for, and implementation of the Medical Device Regulation (EU) 2017/745 (MDR) [1].

Starting on November 26, 2017, conformity assessment organisations seeking notification status as Notified Bodies for the MDR and/or *in vitro* diagnostic medical devices regulation were allowed to send their applications to the responsible national competent authority. At the time of publication of this Technical Bulletin, there are just two Notified Bodies accredited under MDR [1].

EIGA members are concerned about the negative consequences resulting from delays and lack of capacity at notified bodies. Specific concerns are:

- availability of auditors;
- lack of experienced auditors; and
- inefficiencies, that could lead to increased costs.

The above could lead to delays in placing medical devices on the market and a reduction of availability of medical devices.

Current status

At the time of the publication of this technical bulletin, a limited number of Notified Bodies applied for accreditation under the MDR. Among them, less Notified Bodies are able to fulfil the requirements for qualification. This is in mainly related to the following aspects:

- Additional auditors are needed to cover all groups of medical devices within the scope of activities for which the Notified Bodies seek notification, because of “descoping” of the auditors (descoping means losing audit/review scopes compared to the Directive 93/42/EEC [2]), but the time needed to develop a lead auditor starting from new and unexperienced personnel is long;

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- Many more duties than those required by the Directive 93/42/EEC (MDD) [2] have to be carried out by Notified Bodies, such as the assessment of additional reports [3], or the obligations related to the use of the EUDAMED database under MDR;
- Due to new requirements of the MDR, many software products will need certification by a Notified Body; this will result in the need for software experts/auditors of which there are a limited number available.

Moreover, the time required for the notification process is longer than expected.

As a result, at the time of publication of this Technical Bulletin only two Notified Bodies have been notified under the MDR [1], one of them being located in the UK. It must be noted that depending on the type of Brexit, certificates issued by a non-EU Notified Bodies could no longer be valid.

Additionally, even in the case Notified Bodies will provide the required resources and capacity to cover all industry sectors, the current lack of documents needed for the application of the MDR [1] by all the operators involved, for example, implementing acts or guidance documents, could lead to different interpretations on the provisions of the regulation, such as on classification of the devices.

Consequences for Medical Device Industry

Based on the above situation of Notified Bodies, the consequences for medical device manufacturers are potentially:

- longer times for the certification process, than in the past;
- increasing number of formal findings during the audits, due to potential uncertainty in the interpretation of the requirements and to new and unexperienced auditors;
- need to change the Notified Body, in the case it no longer covers the required scope(s) of the certification, along with the difficulties to identify a new Notified Body; and
- increase of costs, due to the limited capacity of the Notified Bodies and the additional tasks they have to carry out.

Medical Device manufacturers are strongly recommended to check the progress of their current Notified Body in becoming notified under MDR [1] and be prepared to identify an alternative Notified Body in the event of a delay in becoming notified under the new regulations.

The availability of resources such as qualified auditors, especially due to the descoping could also have a major impact. In certain fields of the Medical Device industry where resources with certain auditing and review scopes are scarce. For example, with medical device gases, the availability of experienced auditors and technical reviewers could lead to further resource shortages at Notified Bodies. These factors could lead to unacceptable delays.

EIGA interpretation of codes for medical device gases and medical gas pipeline systems

The Commission Implementing Regulation (EU) 2017/2185 [4] sets out the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 [1].

The following table shows the possible applicable codes to medical device gases and medical gas pipeline systems (MGPS), based on the interpretation of EIGA members.

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CODE	DESCRIPTION	MGPS	Liquid CO_2	Gaseous CO_2	Liquid N_2	Liquid N2O	Ophthalmic gases	Argon
MDA 0303	Active non-implantable devices utilising hyperthermia / hypothermia		●		●	●		
MDA 0314	Active non-implantable devices for processing and preservation of human cells, tissues or organs				●			
MDA 0316	Medical gas supply systems and parts thereof	●						
MDN 1104	Non-active soft tissue and other implants						●	
MDN 1206	Non-active non-implantable ophthalmologic devices						●	
MDN 1213	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route			●				
MDN 1214	General non-active non-implantable devices used in health care and other non-active non-implantable devices						●	●
MDT 2001	Devices which require metal processing	●						
MDT 2011	Devices which require packaging, including labelling		●	●	●	●	●	●
MDT 2012	Devices which require installation, refurbishment	●						

References

[1] Regulation (EU) 2017/745 *of the European Parliament and of the Council of 5 April 2017 on medical devices* (MDR)

[2] Council directive 93/42/EEC of 14 June 1993 *concerning medical devices* (MDD)

[3] NBOG BPG 2017-1 – NBOG *Best Practice Guide Designation and notification of conformity assessment bodies*

[4] Commission Implementing regulation (EU) 2017/2185 of 23 November 2017 *on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council*.

Nando (New Approach Notified and Designated Organisations) Information System-

http://ec.europa.eu/growth/tools-databases/nando/

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