

April 2021



Q&A Document on the application of transitional provisions for certification of class D in vitro diagnostic medical devices

According to Regulation (EU) 2017/746 on in vitro diagnostic medical devices (the IVDR), as part of conformity assessment of class D in vitro diagnostic medical devices (IVDs), the manufacturer must submit an application to a notified body. In addition to the assessment by the notified body, under certain conditions particular elements may be reviewed by an expert panel and/or tested by an EU reference laboratory (EURL).

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-4_en.pdf

April 2021



Guidance on standardisation for medical devices

This document aims to provide guidance on different aspects related to standards in the medical devices sector in support of the requirements laid down in the applicable EU legislation, taking into account its specificities.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_5_en.pdf

April 2021



Q&A regarding clinical investigation according to Regulation (EU) 2017/745

This document is intended for sponsors of clinical investigations of medical devices conducted within the scope of the MDR. The document answers important questions for manufacturers and sponsors, such as:

- What is the difference regarding the Clinical Investigation under the MDD and MDR
- The regulatory pathway to conduct a clinical investigation to collect clinical data
- Does a manufacturer of devices without a medical purpose (Annex XVI of the MDR) have to conduct clinical investigations?
- How is a substantial modification defined?

It also provides a flowchart in Annex I for the regulatory pathway

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-6_en.pdf

May 2021



Notice to manufacturers and authorised representatives on the impact of genetic variants on SARS-CoV-2 in vitro diagnostic medical devices

This notice is addressed to manufacturers of in IVDs with the intended purpose to detect and/or quantify markers of SARS-CoV-2 infection. The notice underlines the manufacturers' responsibilities to continually assess the impact of newly identified genetic variants of SARS-CoV-2 on the capability of those IVDs to meet their performance, risk and safety claims.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-7_en.pdf

May 2021



The MDCG released Clinical investigation application/notification documents

In the absence of EUDAMED, a series of clinical investigation application/notification docs have been created to support clinical investigation procedures with respect to MDR.

These documents include:

- Clinical investigation -application/notification form under the MDR
- Addendum to the clinical investigation application/notification form for:
 - Additional investigational device(section 3)
 - Additional comparator device(s) (section 4)
 - Additional investigation site(s) (section 5)
- Clinical investigation supporting documents - Appendix of documents to attach
- Checklist of general safety and performance requirements, Standards, common specifications and scientific advice

Read more:

https://ec.europa.eu/health/sites/default/files/md_sect or/docs/mdcg_2021-8_en.pdf

May 2021



MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers

UDI Assignment: the abovementioned products are expected to be in compliance with the UDI assignment obligations set out in Art 27(3) and Art 29 (1) MDR, applying mandatorily from 26 May 2021, until specific UDI assignment solutions are finalised.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sect or/docs/md_2021-9_en.pdf

May 2021



The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices

Certain principles and terminology set out within the IMDRF N48 Appendixes are not applicable under the MDR/IVDR. The document provides a comparison table explaining the applicable MDR/IVDR principles and terminology that should be applied for compliance. Please note that 'X' in the table indicates that this IMDRF principle/terminology is not applicable under either the MDR and/or IVDR.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-10_en.pdf

May 2021



Guidance on Implant Card – 'Device types'

According to Article 18 (a) of the MDR, the manufacturer of an implantable medical device shall provide together with the device, information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer.

This document provides a non-exhaustive list of implantable medical 'device types' in order to aid manufacturers in allocating an appropriate term for this requested information.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-11_en.pdf

May 2021



FAQ on the European Medical Device Nomenclature (EMDN)

This FAQ documents answers the following questions:

- What is the European Medical Device Nomenclature (EMDN)?
- How was the EMDN created?
- What are the key principles of EMDN?
- How do I gain access to the EMDN?
- How is the EMDN structured?
- Which level of the EMDN should I use to assign a term to my device?

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-12_en.pdf

May 2021



Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional

This document provides guidance to Member States and other relevant parties on the application of certain MDR provisions during the absence of EUDAMED. To that end, this guidance intends to describe harmonised administrative practices and alternative technical solutions for the exchange of information until EUDAMED becomes fully functional. The proposed practices and solutions aim to enable Member States and other relevant parties to meet their obligations under the MDR effectively while minimising any potential additional burden.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/2021-1_guidance-administrative-practices_en.pdf

July 2021



Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorized representatives and importers

This Q&A is aimed at addressing questions relating to the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 of the MDR and/or Article 28 of the IVDR. It also clarifies the cases where an Actor ID is issued instead of an SRN.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021-13_q-a-actor_registr_eudamed_en.pdf

July 2021



Explanatory note on IVDR codes

The lists of codes and corresponding types of IVDs established by Regulation 2017/2185 (Annex II) takes into account various device types which can be characterised by design and intended purpose including companion diagnostics devices, devices for self-testing or for near patient testing, as well as by manufacturing processes and technologies used, such as sterilisation. These lists of codes should allow a multi-dimensional application to all typology of devices. This will ensure that NB as well as the personnel assigned to conformity assessment are fully competent for the devices they are required to assess.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021-14-guidance-ivdr-codes_en.pdf

July 2021



The MDCG released 4 Application Forms for NB to request designation under the MDR and IVDR

- 1) Application form to be submitted when applying for designation as notified body under the medical devices Regulation **(MDR)**

Download it:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-15_en.docx

- 2) Application form to be submitted when applying for designation as notified body under Regulation (EU) 2017/746 on in vitro diagnostic medical devices **(IVDR)**

Download it:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-16_en.docx

- 3) Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 **(MDR)**

Download it:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-17_en.docx

- 4) Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 **(IVDR)**

Download it:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-18_en.docx

July 2021



Guidance note integration of the UDI within an organisation's quality management system

UDI (composed of the UDI-DI and UDI-PI) and Basic UDI-DI assignment, and management of the UDI-related information can impact many other lifecycle QMS processes. The manufacturer could establish a UDI implementation plan and use appropriate implementation tools as described in its QMS to allow correct assessment/decisions to be made and the proper documented evidence to be created, to ensure compliance with the Regulations regarding the UDI-system. See the original document to set up a plan.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-19_en.pdf

July 2021



Instructions for generating CIV-ID for MDR Clinical Investigations

For clinical investigations under MDR the Competent Authorities (CAs) use Eudamed to obtain a Union-wide unique single identification number (the 'CIV-ID'), upon submission of the required information to Eudamed. To do so, the below steps need to be followed:

- STEP 1: Search/generate a Clinical Investigation ID, ('CIV ID')
- STEP 2: Enter the mandatory details of the related Clinical Investigation. To allow the correct registration, search and identification of the MDR Clinical investigations in Eudamed, 3 rules apply:

- 1. Always start the Clinical Investigation title with “MDR” (“MDR – title”, i.e.: MDR - Detecting Traumatic Intracranial Hemorrhage with Microwave Technology)
- 2. Always enter the Sponsor details (this is optional in Eudamed2)
- 3. Do not indicate the risk class of the investigational device (MDR risk classes are not present in Eudamed)
- STEP 3 – Confirm the Clinical Investigation.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-20_en.pdf

August 2021

Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices

The content of this guidance document is envisaged to form the basis for common specifications to be adopted according to Article 9 of Regulation (EU) 2017/746 in the coming months. The content may be adapted to take account of changing circumstances and increasing scientific and technical knowledge, as the COVID-19 pandemic continues to evolve.

Read more:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-21_en.pdf



Chemsafe wishes you happy Summer Holidays!

Please note that our offices will be closed from 13th to 22th of August
