NEWSLETTER March 2020

Brussels, 10.01.2020

Summary of safety and clinical performance - A guide for manufacturers and notified bodies

The European Commission has released clarifications regarding the basic principles and the structure of the Italian "Classificazione Nazionale Dispositivi" which will be used as the basis for the EMDN as well as another document which states the EC intend to map the EMDN to the Global Medical Device Nomenclature

Read more:
https://ec.europa.eu/docsroom/documents/39007/attachments/1/translations/en/renditions/native
https://ec.europa.eu/docsroom/documents/39009/attachments/1/translations/en/renditions/native

Brussels, March 2020

Guidance on BASIC UDI-DI and changes to UDI-DI

"This guidance is intended to provide a clarification on the notion of Basic UDI-DI, its use in relevant documentation and the factors triggering UDI-DI changes"

Read more:
https://ec.europa.eu/docsroom/documents/40322/attachments/1/translations/en/renditions/native

Brussels, March 2020

Guidance document – How to applicate Article 18 relating to Implant Card

"An implant card (IC) is required by the MDR (Regulation 2017/745). This document describes the intended use, content and information to be provided by the manufacturer and a definition of fields to be completed by the implanting healthcare institutions or healthcare providers according to national law in Member States, which must be considered by the individual Member State when implementing Article 18 MDR"

Read more:
https://ec.europa.eu/docsroom/documents/40321/attachments/1/translations/en/renditions/native

Brussels, March 2020

Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software

"This guidance provides a framework for the determination of the appropriate level of clinical Evidence required for Medical Device Software (MDSW) to fulfil the requirements set out in The MDR and IVDR. In order to promote global convergence, this document takes into account certain concepts outlined in International Medical Device Regulators Forum (IMDRF) guidance documents"

Read more:
https://ec.europa.eu/docsroom/documents/40323/attachments/1/translations/en/renditions/native

Brussels, March 2020

Class I Transitional provisions under Article 120 (3 and 4) – (MDR)

"*This document describes relevant information to be included in the manufacturer's Declaration of Conformity (DoC) of Class I devices (devices which are non-sterile or do not have a measuring function) that are required to have certificates after 26 May 2024 according to the MDR"*

Read more:
https://ec.europa.eu/docsroom/documents/40324/attachments/1/translations/en/renditions/native

Brussels, March 2020

Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD

"This Document clarifies which changes to a device should be considered a "significant changes in design or intended purpose" under Article 120(3) of the MDR. It further stats that no issuing of new MDD/AIMDD certificates, including modified, amended or supplemented certificates, is allowed. If the manufacturer makes a "significant change in design or intended purpose", the implementation of such a change would prevent the manufacturer from continuing to place that device on the market under the Directives. Finally, the guidance includes decision flowcharts to help manufacturers decide whether or not a change to a device will be considered significant.

Read more:
https://ec.europa.eu/docsroom/documents/40301/attachments/1/translations/en/renditions/native

March 2020

A total of 12 NBs is able to certify devices under the European Medical Devices Regulation 3 of which obtained designation also for IVDR.

- *BSI (UK)*
- *BSI NL (The Netherlands)*
- *CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft (Hungary)*
- *Dare!! (The Netherlands)*
- *DEKRA (Germany)*
- *DEKRA (The Netherlands)*
- *DNV GL Presafe AS (Norway)*
- *IMQ (Italy)*
- *MedCert (Germany)*
- *NSAI (Ireland)*
- *TÜV SÜD (Germany)*
- *TÜV Rheinland (Germany)*

March 2020

EU Commission Recommendation 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat

"The Commission invites all economic operators, as well as notified bodies and market surveillance authorities to deploy all the measures at their disposal to ensure that the supply of PPE and medical devices throughout the EU market will match the increasing demand. Hence the following recommendation document.."

Read more:
https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020H0403&from=EN#d1e39-1-1

March 2020

Ongoing Discussion on postponing MDR for 12 months

Due to the Coronavirus Crisis the European Commission has issued a statement that they are working on a proposal to delay the date of application of the Medical Devices Regulation (MDR) by one year. This will go to the European Parliament at the beginning of April

Read more:
https://ec.europa.eu/health/sites/health/files/docs/20200325_news_md_en.pdf