NEWSLETTER JUNE 2020

Brussels, 17.04.2020

The MDR is postponed to May 2021

Due to the Coronavirus crisis the European Commission has adopted the proposal to postpone by one year the date of application of the Medical Device Regulation.

Read more:
https://www.europarl.europa.eu/news/en/press-room/20200415IPR77113/parliament-decides-to-postpone-new-requirements-for-medical-devices

Brussels, 17.04.2020

New Guidance on COVID-19 IVD test performance and validation

"It's a collection and review of publicly available information from manufacturers on commercially available devices for COVID-19 and of performance assessment studies of test methods and devices for COVID-19. This report proposes performance criteria for different types of COVID-19 test methods and devices"

Read more:
https://ec.europa.eu/docsroom/documents/40805?locale=it

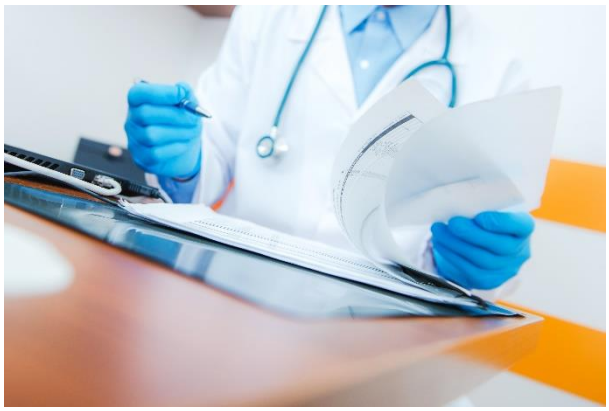
Brussels, 24.04.2020

Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies

"This MDCG guidance covers the demonstration of equivalence, based on data pertaining to an already existing device on the market, for the purpose of CE-marking under the MDR. One of the purposes of this document is to highlight the differences between the MDR and the MEDDEV 2.7/1 rev.4 "

Read more:
https://ec.europa.eu/docsroom/documents/40903/attachments/1/translations/en/renditions/native

Brussels, 24.04.2020

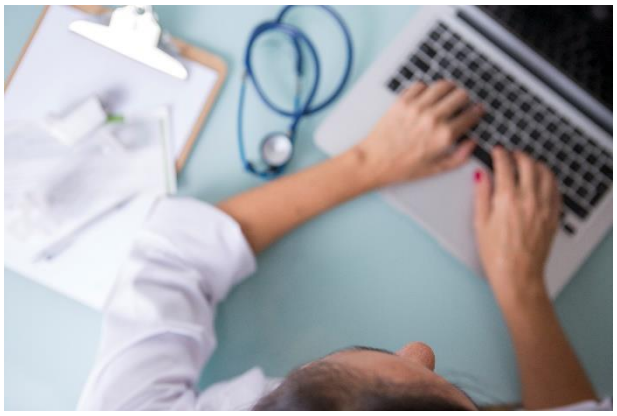


Clinical evidence needed for legacy medical devices previously CE marked under MDD

"This MDCG document seeks to provide guidance for clinical data providing sufficient clinical evidence necessary to demonstrate conformity with the relevant GSPR, as per Article 61(1) MDR, for legacy devices CE marked with respect to Directives 93/42/EEC (MDD) or 90/385/EEC (AIMDD)."

Read more:
https://ec.europa.eu/docsroom/documents/40904/attachments/1/translations/en/renditions/native

Brussels, 24.04.2020



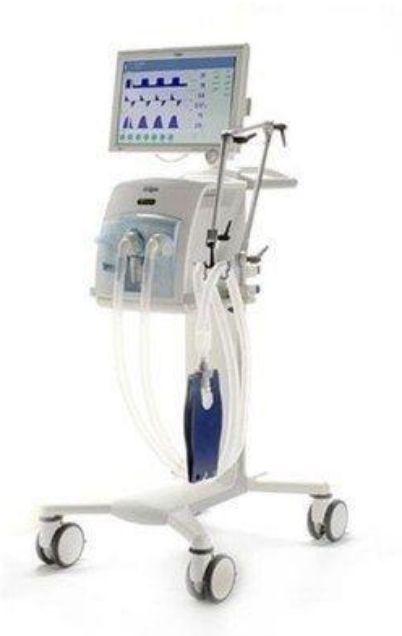
Post-market clinical follow-up (PMCF) Plan and Report Templates

"The MDR considers the post-market clinical follow-up (PMCF) as a continuous process that updates the clinical evaluation and that shall be addressed in the manufacturer's post-market surveillance (PMS) plan."

PMFC Plan Template:
https://ec.europa.eu/docsroom/documents/40905/attachments/1/translations/en/renditions/native

PMFC Report Template:
https://ec.europa.eu/docsroom/documents/40906/attachments/1/translations/en/renditions/native

Brussels, 27.04.2020



Regulatory Requirements for Ventilators and related Accessories

"Under the current COVID-19 context, the demand for ventilators and related accessories has rapidly increased. Therefore, this document intends to outline the different regulatory options for placing these devices on the EU market indicating their feasibility to allow short-term supply"

Read more:
https://ec.europa.eu/docsroom/documents/40941/attachments/1/translations/en/renditions/native

15.05.2020

The Medical Device Coordination Group has released two new documents on the safety reporting in clinical investigations of medical devices in the absence of Eudamed

Read more:
https://ec.europa.eu/docsroom/documents/41183/attachments/1/translations/en/renditions/native

Template:
https://ec.europa.eu/docsroom/documents/41184/attachments/1/translations/en/renditions/native

18.05.2020

The EU Commission has released a Questions and Answers document on personal protective equipment

"How to verify that medical devices and personal protective equipment can be lawfully placed on the EU market and thus purchased and used – also in the COVID-19 context"

Read more:
https://ec.europa.eu/docsroom/documents/41385/attachments/1/translations/en/renditions/native

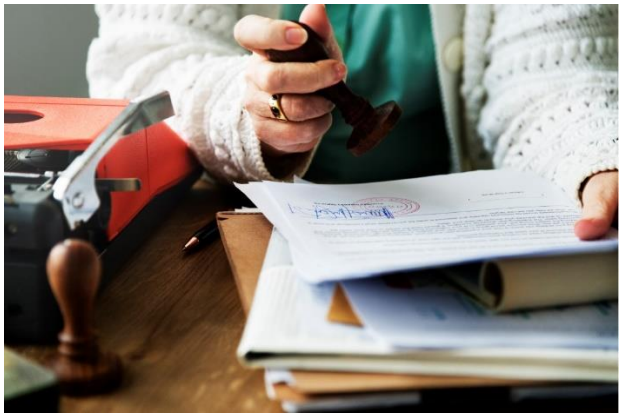
19.05.2020

Questions and Answers document regarding the Implementation of the new Manufacturer Incident Report (MIR) Form

This Question and Answer (Q&A) document is intended to help companies to adapt their IT system to the new MIR form by indicating the main changes compared to previous MIR form and by tackling typical IT questions.

Read more:
https://ec.europa.eu/docsroom/documents/41322/attachments/1/translations/en/renditions/native

28.05.2020



The MDCG has released a guidance on the renewal of designation and monitoring of notified bodies under Directives 90/385/EEC and 93/42/EEC

This guidance covers the following activities performed by designating authorities:

- *renewal of designation under the Directives of notified bodies whose designation expires in the period from 26 May 2020 to 25 May 2021;*
- *surveillance activities to be performed by designating authorities in accordance with the Implementing Regulation under COVID-19 related restrictions, notably quarantine orders and travel restrictions.*

Read more:
https://ec.europa.eu/docsroom/documents/41421/attachments/1/translations/en/renditions/native

03.06.2020

Implementation Rolling Plan for MDR and IVDR

This rolling plan contains a list of identified essential implementing acts and other relevant initiatives that the Commission has adopted or intends to adopt in the future.

Read more:
https://ec.europa.eu/docsroom/documents/41501/attachments/1/translations/en/renditions/native

10.06.2020

Guidance on devices incorporating a substance which may be considered a medicinal product and on devices manufactured using TSE susceptible animal tissues

The MDCG has released a guidance which offers consultations for a substance which may be considered a medicinal product and which has action ancillary to that of the device (including human blood derivative) and consultations for medical devices containing TSE susceptible animal tissue under the MDR, where such a consultation took place under the MDD or AIMDD

Read more:
https://ec.europa.eu/docsroom/documents/41622/attachments/1/translations/en/renditions/native

12.06.2020

Manufacturer incident report 2020

Get the manufacturer incident report (MIR) template in PDF here

MIR:
https://ec.europa.eu/docsroom/documents/41681/attachments/1/translations/en/renditions/native

https://ec.europa.eu/docsroom/documents/41682/attachments/1/translations/en/renditions/native

June 2020

TÜV SÜD is designated under IVDR

The German institute is the fourth notified body designated under the forthcoming regulation on in vitro diagnostics (IVDR)

June 2020

Guidance on UDI for systems and procedure packs

The MDCG released a guidance document on the obligations for procedure pack producer, that combine medical devices with other products, in order to place them on the market as either a system or a procedure pack. That combination is intended to achieve a specific medical purpose

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_guidance_udi_spp.pdf

June 2020

Guidance on the application of ISO 14971

The revised and updated version of Technical Rule ISO/TR 24971:2020-06 regarding ISO 14971 - Application of risk management to medical devices has been released