NEWSLETTER SEPTEMBER 2020

Brussels, July 2020

Clinical Evaluation Assessment Report Template

"This MDCG template represents the minimum content for a CEAR and needs to be incorporated into the process and procedures of the notified body. The CEAR shall also make a recommendation to support a final review and a final decision to be taken by the notified body "

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-13-cea-report-template_en.pdf

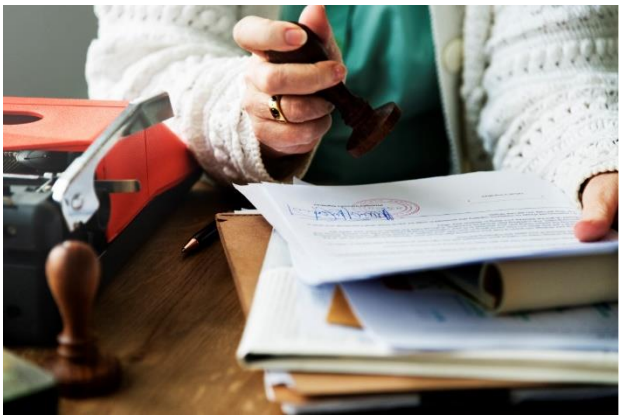
Brussels, July 2020

The EU Commission has released a Questions and Answers document on the conformity assessment procedures for 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/42311/attachments/1/translations/en/renditions/native

Brussels, August 2020



Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the MDR and IVDR

"The purpose of this document is to provide guidance to notified bodies on how to take into account Medical Device Regulatory Audit Reports issued by MDSAP auditing organisations when performing surveillance audits"

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-14-guidance-mdsap_en.pdf

Brussels, August 2020

MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States

"the Commission has confirmed its readiness to deploy the actor registration module as of 1 December 2020. The members of the MDCG strongly encourage the use of the actor registration module by all relevant actors on their territories, including the use of the single registration number by actors as stipulated in the MDR"

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/2020-15-position-paper-actor-registration-module_en.pdf

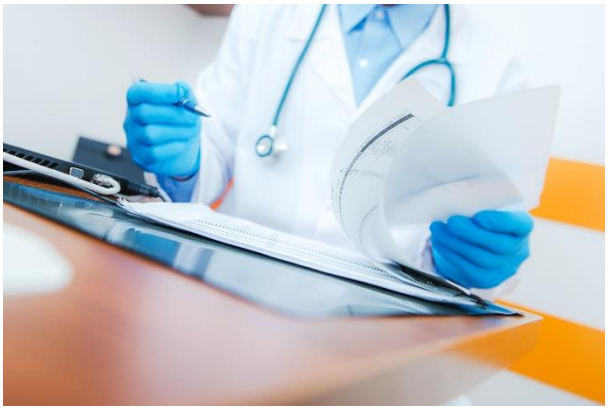
August 2020

The European Commission has released FAQs - Unique Device Identification (UDI) System

This brief leaflet answers some of the most frequently ask questions concerning the UDI

Read more:
https://ec.europa.eu/docsroom/documents/42641/attachments/1/translations/en/renditions/native

August 2020

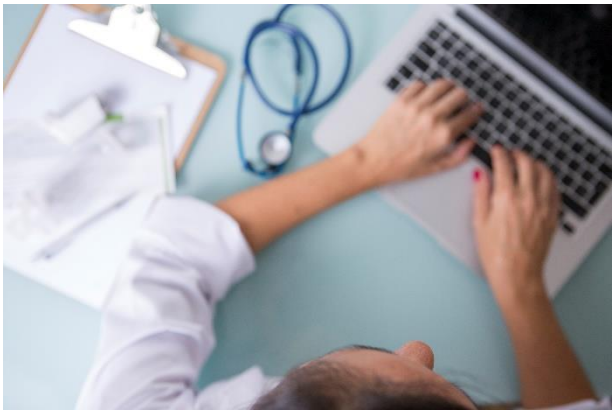


The European Commission laying down rules for the application of Regulation (EU) 2017/745 as regards common specifications for the reprocessing of single-use devices

The MDR allows reprocessing of single-use devices only where it is permitted by national law. As regards single-use devices that are reprocessed and used within a health institution, MDR allows Member States not to apply all of the rules relating to manufacturers' obligations laid down in that Regulation. One of the conditions for such reprocessing is that it is performed in accordance with common specifications.

Read more:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1207&from=EN

September 2020



The FDA has released a new guidance to provide further clarification and updated information on the use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" to support applications to FDA

This guidance document is meant to assist industry in preparing Premarket Applications (PMAs), Humanitarian Device Exceptions (HDEs), Investigational Device Exemption (IDE) Applications, Premarket Notifications (510(k)s), and De Novo requests for medical devices that come into direct contact or indirect contact with the human body in order to determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body.

Read more:
https://www.fda.gov/media/85865/download

September 2020

Three new NBs are able to certify devices under the European Medical Devices Regulation, bringing the total to 17 .

- *GMED (France)*
- *DQS Medizinprodukte GmbH (Germany)*
- *3EC International a.s. (Slovakia)*