NEWSLETTER MARCH 2021

January 2021

ISO 10993-23:2021 Biological evaluation of medical devices - Tests for irritation

The irritation potential of a medical device or its components can be predicted either in vivo or in vitro, if qualified for use with medical devices.
This new document reinforces the animal welfare aspects already mentioned in ISO 10993-2, emphasizing the 3R's (replacement, reduction, and refinement of animal studies) for the biological evaluation of medical devices.

Read more:
https://www.iso.org/standard/74151.html

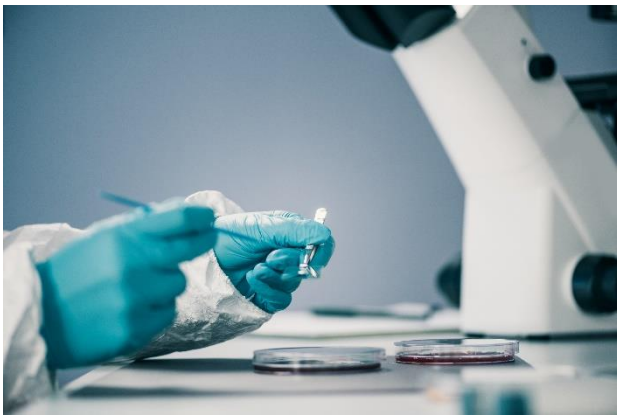
January 2021

ISO 10993-12:2021 Biological evaluation of medical devices - Sample preparation and reference materials

This document specifies requirements and gives guidance on the procedures in the preparation of samples and the selection of reference materials for medical device testing primarily in biological test systems primarily in accordance with one or more parts of the ISO 10993 series.

Read more:
https://www.iso.org/standard/75769.html

January 2021



The IMDRF released the document - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Its purpose is to assist a manufacturer to allocate it's In Vitro Diagnostic (IVD) medical device to an appropriate risk class using a set of harmonized principles. Regulatory Authorities have the responsibility of ruling upon matters of interpretation for a particular medical device. This document should be read in conjunction with the GHTF document "Principles of Conformity Assessment for IVD medical devices" that recommends conformity assessment requirements appropriate to each of the four (4) risk classes proposed herein.

Read more:
http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-wng64.pdf

February 15th, 2021

Official document of the European Union on how to identify Legacy Devices in EUDAMED

This document contains the details of how Legacy Devices will be identified in EUDAMED and the way the different Unique Device Identifiers for the Legacy Devices will be generated/assigned.

Read more:
https://ec.europa.eu/health/sites/health/files/md_eudamed/docs/legacy_dvc_management_en.pdf

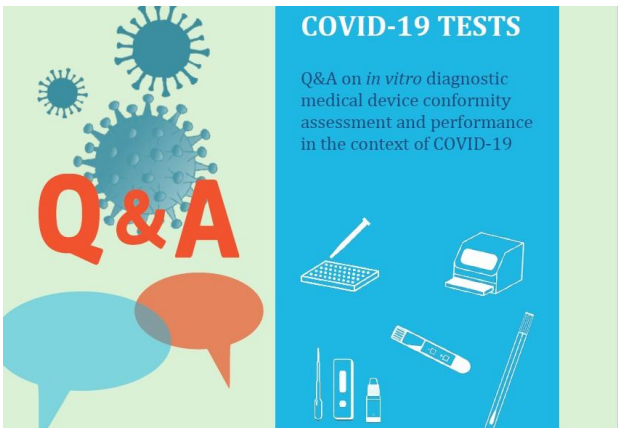
February 2021

MDCG Guidance on harmonized administrative practices and alternative technical solutions until EUDAMED is fully functional.

This document provides guidance on the application of certain MDR provisions during the absence of EUDAMED to enable Member States and other relevant parties to meet their obligations under the MDR effectively. It is important to remember that all MDR requirements will apply as relevant, this means the obligation of generating certain information (for example: UDI, Summary of Safety and Performance (SSCP), Periodic safety update report (PSUR)) even if they cannot jet be uploaded to EUDAMED.

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

February 2021



The European Commission released a Q&A on in vitro diagnostic medical device conformity assessment and performance in the context of COVID-19

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/covid-19_ivd-qa_en.pdf

February 2021

The MDCG released a Guidance on state of the art of COVID-19 rapid antibody tests.

The MDCG guidance intends to establish elements on the current state of the art for COVID-19 rapid antibody tests. Specifying that in this particular context, the state of the art may be seen as the minimum expected from devices being placed on the market at the time of publication of this document.
It is crucial that the manufacturer clearly specifies the device's intended purpose, considering what levels of performance are needed and what aspects of the state of the art are relevant. Keeping in mind to continuously update/revise the device's performance data and/or adjust the intended purpose with new available data.

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_2021-2_en.pdf

March 2021

The European Commission released an infographic to illustrate the decision-making process of whether your Software is a Medical Device

Read more:
https://ec.europa.eu/health/sites/health/files/md_newregulations/docs/notifiedbodies_overview_en.pdf

March 2021

MDCG released a Questions and Answers on Custom-Made Devices & considerations on Adaptable medical devices and Patient-matched medical devices.

This Q&A aimed at addressing the most pertinent questions relating to custom-made devices falling under Regulation (EU) 2017/745 on medical devices (MDR).

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_2021-3_en.pdf

March 2021

One new NB (SGS FIMKO OY – Finland) can certify devices under the European Medical Devices Regulation, bringing the total to **19**.

For the IVDR there has been a withdrawal from BSI Assurance UK Ltd bringing the total back to only **4**!

Chemsafe wishes you happy Easter!

Please note that our offices will be closed from 01 th to 06th of April

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