Client Newsletter

Medical Device Regulatory Updates

PUBLISHED MDCG GUIDELINES:

- There are new guideline documents published by MDCG which has impact on the industry. Please follow this link and perform impact assessment on your organisation.

STATE OF PLAY EUDAMED?

- The new MDCG Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional includes e.g. information on:
  - The SSCP shall be made available to the public upon request without undue delay or the manufacturer shall specify where it is made available to the public.
  - Manufacturers should report serious incidents and field safety corrective actions to the respective/relevant national vigilance systems.
  - Manufacturers must submit trend reports to the respective / relevant national vigilance systems. The current Trend report form should be used until its updating for MDR compliance.
- The module on UDI/device registration (second module) and the module on Certificates and Notified Bodies (third module) has been del and will become available by September 2021. Afterwards, the remaining modules will be displayed as soon as they are functional

WHAT HAPPENS ON THE 26TH OF MAY 2021?

- Class I devices according to MDR shall be placed on the market fully in conformity with MDR
- Manufacturing of custom-made devices shall be in compliance with MDR
- Systems and procedure packs shall be placed on the market fully in conformity with MDR
- Device model not previously assessed for conformity market shall be fully compliant with MDR in order to be placed on the market

Which includes, among other things

- UDI needs to be assigned for all MDR devices
  - UDI carrier in place for implants and class III MDR devices
- Registration should be done according to MDR – national measures until EUDAMED is fully functional
- A person responsible for regulatory compliance (PRRC) shall be appointed for the manufacturing of MDR devices
- Measures to ensure traceability shall be in place for MDR devices
- Measures to ensure that only correct marketing claims are made shall be in place for MDR devices

LEGACY DEVICES

- Devices covered by the transitional provisions in 120.3
  - Devices with a valid certificate according to directive 93/42/EEC (MDD)
  - Devices in class I according to MDD, with a declaration of conformity drawn up before 26 May 2021 but will be subject to assessment by notified body according to MDR (reusable surgical instruments or class IIa, IIb or III)
- Conditions
  - Lockdown for new DoC:s for devices in class I according to MDD that require assessment by notified body according to MDR
  - Lockdown for significant changes (see MDCG 2020-3 on significant changes)
  - Art 120(3) of the MDR lays down that the requirements of the MDR relating to post market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to legacy devices placed on the market after the application date of the MDR in place of the corresponding requirements of the Directives.

Need to remember that legacy devices are placed on the market according to MDR but need to meet the requirements in MDD/AIMDD and will be subject of appropriate surveillance.

STANDARDS

- ISO 10993-12 Biological Evaluation of Medical Devices has just been published and the main changes in this release is:
  - The scope is changed to cover extraction related to biological evaluation tests only.
  - The extraction condition table was revised as well as Annex D regarding exhaustive extraction, in line with the new ISO10993-18 standard.
  - Harmonization of definitions with ISO 10993-18
- ISO 10993-23 Biological evaluation of medical devices — Part 23: Tests for irritation
  - This document specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation. The tests are designed to predict and classify the irritation potential of medical devices, materials or their extracts according to ISO 10993-1 and ISO 10993-2. This document includes:
    - Pre-test considerations for irritation, including in silico and in vitro methods for dermal exposure
    - Details of in vitro and in vivo irritation test procedures
    - Key factors for the interpretation of the results

- Amendment 1 (2020-06) to the IEC 62366-1 standard for Usability Engineering published
    - The international standard IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering (UE) to medical devices has been amended. A consolidated version (edition 1.1) is available. The changes presented in the Amendment 1 (A1) do not changes the process of UE. They are merely a further strengthening of the link with risk management as defined by ISO 14971:2019. As a result of this alignment, edition 1.1 of IEC 62366-1 should be used in conjunction with ISO 14971:2019.

EXPERT PANELS APPOINTED BY THE COMMISSION AS ADVISORS IN THE FIELD OF MEDICAL DEVICES

One step in the MDR / IVDR compliance assessment for certain high-risk products is that an expert panel is given the opportunity to review the clinical evaluation report (MDR) or the performance evaluation report (IVDR) and issue a statement.

The European Commission has finally appointed several experts who are available to be part of panels and has published information on the website. The experts are divided into different specialist areas, today it is 12 different fields of expertise. All the members signed the declaration of commitment and confidentiality, follow this link to see who they are. Support documents for the work within the panels have also been developed.

Priority task for the panels is the assessment of clinical evaluation reports during the assessment of conformity. The expert panels are estimated to be operational by mid-April 2021.

The expert panels in the field of medical devices now accept submissions from notified bodies for the Clinical Evaluation Consultation Procedure.

UK APPROVED BODY

There will be no mutual recognition of EU Notified Bodies and therefor IMNB are currently under discussions with MHRA for applying to become a UK Approved Body.

We aim to submit our application during 2021 and be approved well in time for the end grace period, related to CE mark. A smooth designation process should take approx. 6 months but is dependent on a number of factors.

ONGOING GUIDANCE DEVELOPMENT AND DELIVERABLES OF MDCG SUBGROUPS – MARCH 2021

On this link there is a list of the planned activities for MDCG and the expected guidance documents to be released, we are looking forward to some new guidance's especially the Guidance on appropriate surveillance according to MDR article 120 (3) and the guidance on certification according to MDR article 16 that will be launched very soon!

EUC IMPLEMENTATION ROLLING PLAN

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. The plan was updated in April, please follow this link and have a look what is expected.

IS YOUR SOFTWARE A MEDICAL DEVICE?

Decision steps to assist qualification of Medical Device Software (MDSW) was published by European commission. Follow this link to learn more.

NOTIFIED BODIES ENCOURAGE APPLICATION AS SOON AS POSSIBLE TO ALLOW TRANSITION

To avoid potential gap in certification between MDD and MDR we recommend you to apply for MDR 2017/745 as soon as you are ready. Please read Team NB statement on this link.

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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.