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MDR implementation – State of Play

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T-69 days and counting…

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Today's specials

- EUDAMED
- UDI
- Notified bodies
- Guidance documents
- Expert panels
- National legislation – upcoming
- National legislation – in place
- As of 26 May 2021…
- …which means that
- Legacy devices
- How to keep up

EUDAMED

- Modules published step-wise for voluntary use – endorsed and encouraged by the Swedish MPA
  - Does **not** replace the requirements on registration in national legislation
- Actor registration is open, SRN:s are issued
  - 1200 actors registered, 50 SRN:s are issued in Sweden
  - https://ec.europa.eu/health/md_eudamed/actors_registration
- ”Devices” and ”Certificates” are the next modules scheduled for release
  - Latest estimate: Q3/Q4 2021
- Target date for declaration of full functionality: Still 26 May 2022

EUDAMED

- Upcoming modules
  - Actor input: Vigilance, Clinical Investigations/Performance Studies
  - Authority input: Market Surveillance
- MDCG 2021-1: Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
  - Some workarounds already in place at the Swedish MPA (registrations, application for clinical trials, incident reporting…)
  - Analysis ongoing to establish if, and which, new measures that need to be taken care of
- Target date for declaration of full functionality: Still 26 May 2022

UDI

- Assignment of UDI:s are not dependent on EUDAMED
- UDI is required for devices placed on the market according to MDR from 26 May 2021
- Issuing entities have been appointed since Implementing decision 2019/939 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019D0939)
  - GS1 AISBL
  - Health Industry Business Communications Council (HIBCC)
  - ICCBBA
  - Informationsstelle für Arzneispezialitäten — IFA GmbH
- A separate webpage at the site of the EU commission (FAQ, info on UDI format)
  - https://ec.europa.eu/health/md_topics-interest/unique_device_identifier_en
- A number of guidance documents from MDCG
  - A separate section on https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

Notified bodies

- 19 NB:s for MDR notified in NANDO
  - 1 Swedish NB: Intertek Medical Notified Body AB (2862)
- 1 NB candidate recently recommended by MDCG for notification

- Ongoing assessment of NB candidates
  - In total: 29 applications are still in progress for notification according to MDR
  - Early stages: 9 applications, 7 submitted and 2 where the preliminary assessment report has been drawn up
  - Mid-stage: 12 applications, 10 where the on-site joint assessment has been performed and 2 where the CAPA plan has been submitted to the DA
  - Final stages: 8 applications, 7 where the DA has given an opinion on the CAPA plan and 1 where the JAT has given a final opinion

Guidance documents

- Q&A Custom made devices (CMD) endorsed by MDCG
  - Clarification on the difference between ”true” custom made devices and adaptable devices – may cause changes in the field

- A notable absence: Classification and definitions for borderline to medicinal products
  - Target date 26 May 2021

- Development of further guidance documents
  - https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_ongoing_guidancedocs_en.pdf

- All guidance documents are available at: https://ec.europa.eu/health/md_sector/new_regulations/guidance

Expert Panels

- Experts have been appointed for panels
  - https://ec.europa.eu/health/md_expertpanels/overview_en
- 12 different fields of expertise, including IVD
- Support documents for the work within the panels have been developed

- Priority task for the panels: Assessment of clinical evaluation reports during the assessment of conformity
- Estimated to be operational by mid-April

National legislation - upcoming

- Sorry, will be in Swedish – otherwise lost in translation
- Utgångspunkt: Ds 2019:32
  - https://www.regeringen.se/remisser/2020/01/ds-201932-anpassningar-till-eus-forordningar-om-medicinteknik--del-2/
- Svenska lagar – på lagrådsremiss
  - https://www.regeringen.se/rattsliga-dokument/lagradsremiss/2021/02/anpassningar-till-eus-forordningar-om-medicinteknik--del-2/
- Svenska förordningar – under arbete hos departementet
  - Huvuddelen finns som förslag i Ds 2019:32, kan ej antas före lag
- Svenska föreskrifter – på remiss från Läkemedelsverket
  - https://www.lakemedelsverket.se/sv/lagar-och-regler/kommande-lagstiftning#hmainbody3

National legislation – in place

- Language requirements are laid down in SFS 2020:315 that amends 1993:876
  - User information in Swedish
  - Information submitted to the Swedish MPA: Swedish or English
  - Will probably be transferred to upcoming national legislation
- Fees for application to be designated as a notified body
- Fees for specific procedures according to annex IX, section 5 involving a competent authority for medicinal products

As of 26 May 2021…

- …"plain" 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
- …any device model not previously assessed for conformity market shall be fully compliant with MDR in order to be placed on the market

Legacy devices will be mentioned later

Which means that (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
  - Proposal that medical devices in all risk classes shall be registered with the Swedish MPA
  - Previous registrations in MPA's e-service need to be updated unless already registered as MDR
- …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 any of the directives 93/42/EEC (MDD) or 90/385/EC (AIMDD)
  - 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)
  - Vigilance and PMS according to MDR
  - Registration according to MDR
- Need to remember that legacy devices are placed on the market according to MDR…
  - …but need to meet the requirements in MDD/AIMDD

How to keep up with the latest

- News letter (in Swedish) from the Swedish MPA
  - https://www.lakemedelsverket.se/sv/om-lakemedelsverket/press-och-nyheter/nyhetsbrev/nyhetsbrev-om-medicinteknik
- Website of the Swedish MPA
  - https://www.lakemedelsverket.se/sv/medicinteknik
  - Will be expanded and revised during 2021
- News letter from the EU Commission
  - Subscribe: https://campaign.gopacom.io/mdr-newsletter-subscription
  - Archive: https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_newsletters_en.pdf
- News on the EU Commission website
  - https://ec.europa.eu/health/md-sector/latest_updates_en
  - https://ec.europa.eu/health/md_sector/overview_en

Addendum on 2021-03-18

- From the 26 May 2021, new clinical trials shall be applied for, and conducted, in accordance with MDR. Already active trials will continue according to MDD.

- Standardisation request is accepted by the committe on standards
  - An implementing decision by EU COM will be adopted as soon as possible
  - CEN/Cenelec may still reject it, but all indications are that it will be accepted
  - Harmonised standards **may** be published in OJ already Q2/Q3 2021