




Update from the European Commission on UDI activities


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The new EU Regulations on medical devices (adopted 5 April 2017 and published 5 May 2017)

 { Directive 90/385/EEC on active implantable medical devices
Directive 93/42/EEC on medical devices
Regulation on medical devices (MDR)

 Directive 98/79/EC on in vitro diagnostic medical devices
Regulation on in vitro diagnostic medical devices (IVDR)



Main novelties of the new Regulations (1)

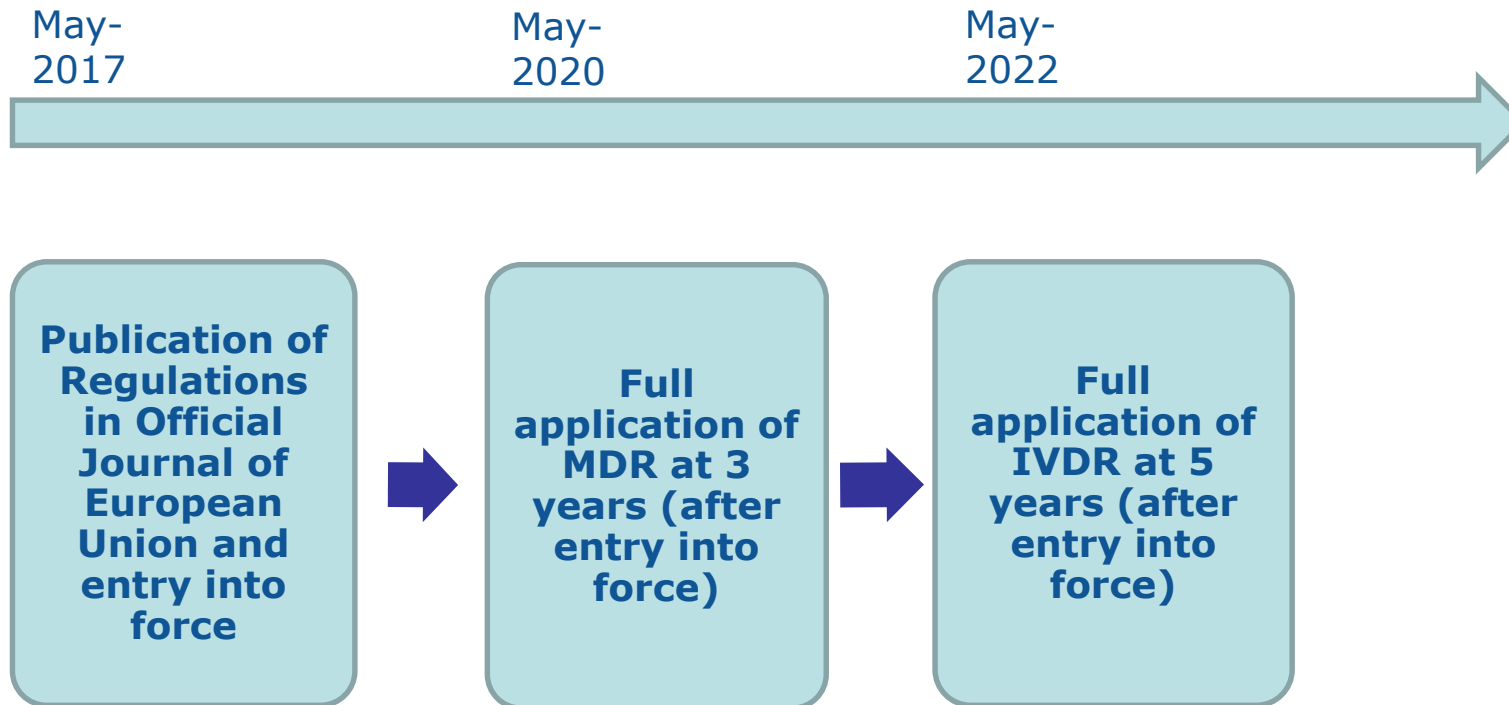
- Inclusion of certain aesthetic devices within the scope.
- EU minimum requirements related to reprocessing of single-use devices.
- Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level.
- Reinforcement of the rules on clinical evaluation (and performance evaluation) and clinical investigation (and performance studies).
- Stricter requirements on the use of hazardous substances for certain devices.
- New classification system for IVDs based on international guidance (80% of IVDs to be assessed by a Notified Body).



Main novelties of the new Regulations (2)

- Reinforced designation and oversight processes of notified bodies.
- Clarification of the role and responsibilities of economic operators.
- Establishment of a comprehensive EU database on medical devices (EUDAMED) with large part of information to be made publicly available.
- Introduction of a UDI system.
- Enhanced cooperation amongst national authorities.
- Stronger coordination role of the European Commission.

Transitional period





Future UDI system within the EU 1/2

Scope:

- Apply to **all medical devices placed on the market except custom-made devices**

Approach:

- Substantially based on internationally recognised principles and guidance but there are some specific EU aspects, namely:
 - The UDI database is part of a more comprehensive medical device database (EUDAMED). UDI is the access key to device-related information in EUDAMED
 - Introduction of an additional unique identifier having an administrative purpose – the Basic UDI-DI (it does not appear on any trade item)
 - EU specific UDI data elements, such as the Single Registration Number identifying the manufacturers/AR (generated by EUDAMED), the future EU medical device nomenclature



Future UDI system within the EU 2/2

Main UDI-related obligations introduced:

- For manufacturers:
 - To assign a UDI to the device and – if applicable – to all higher levels of packaging a UDI before the device is placed on the market
 - To place a UDI carrier on the label of the device and on all higher levels of packaging
 - To ensure that certain defined information is correctly submitted and transferred to the UDI database
- For all economic operators
 - To store the UDI (preferably by electronic means) of all Class III implantable devices – secondary legislation might expand the scope of this provision

Recent developments



Implementation of the UDI system

- *Governance*
 - New MDCG subgroup on UDI has been established (first meeting 21 May 2019)
 - In continuity with current EU Expert Group on UDI, the future MDCG Subgroup on UDI will help preparing regulatory acts/guidance related to UDI implementation and to provide a platform for continuous exchange of views and monitoring of implementation– close cooperation with the EUDAMED UDI WG
 - The two task-forces currently dealing with UDI regulatory guidance and implant card will continue to operate – composition to be possibly revised as a result of transition to MDR
 - A new MDCG subgroup on nomenclature is going to be established.



Designation of UDI issuing entities

- Call for application launched on 21 December, with a deadline of 25 January 2019
- 4 applications received
- Evaluation from the Commission's side completed in February 2019. Discussion with MDCG took place at the 14-15 Feb meeting
- Relevant implementing act to be adopted before 25 May 2019

Guidance on UDI

- Guidance already published:

[MDCG documents](#)

[MDCG endorsed documents](#)

[UDI](#)

| Title | Publication | Date |
|--------------------------------|--|---------------|
| MDCG 2019-1 | MDCG guiding principles for issuing entities rules on Basic UDI-DI | January 2019 |
| MDCG 2019-2 | Guidance on application of UDI rules to device-part of products referred to in Article 1(8), 1(9) and 1(10) of Regulation 745/2017 | February 2019 |
| MDCG 2018-1 v2 | Draft guidance on basic UDI-DI and changes to UDI-DI | February 2019 |
| MDCG 2018-2 | Future EU medical device nomenclature – Description of requirements | March 2018 |
| MDCG 2018-3 | Guidance on UDI for systems and procedure packs | October 2018 |
| MDCG 2018-4 | Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs | October 2018 |
| MDCG 2018-5 | UDI Assignment to Medical Device Software | October 2018 |
| MDCG 2018-6 | Clarifications of UDI related responsibilities in relation to Article 16 | October 2018 |
| MDCG 2018-7 | Provisional considerations regarding language issues associated with the UDI database | October 2018 |

- Next steps:

- Guidance on how to integrate UDI in MF QMS
- Publication of assignment examples
- Guidelines on UDI carriers and marking (based on IMDRF N48)



Work related to nomenclature

- ✓ The Commission, in order to exert its faculty with the maximum possible level of knowledge and information, has established, in cooperation with the MDCG, a process comprising i.a. the establishment of a task-force, composed of regulators from DE, IE, IT, UK – to support the Commission in the selection process
- ✓ 3 providers have spontaneously shown their interest in being possibly considered.
- ✓ The task-force has produced a report which has been discussed by the MDCG on 30 November 2018.
- ✓ Based on the report and orientations provided by the MDCG, the Commission has taken and published its decision in March 2019

Decision on nomenclature

- The CND nomenclature will be made available in the future Eudamed.
- CND will be mapped to GMDN. The correspondence between the nomenclatures will be visible to operators and incorporated in the future database. This will allow all operators registering their device to find CND nomenclature equivalent to a GMDN code.
- The Commission, on the basis of this decision, is keen to support the work of WHO in the field.
- Details related to the governance and operational functioning of the system will be provided in the course of the next few months.



Thank you for your attention !

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