

## Update on EU regulatory developments

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IMDRF – 16 19-21 March 2019 Yekaterinburg, Russia

## The EU single market for medical devices



1. EU



2. EFTA/EEA:
Norway, Liechtenstein, Iceland



3. Turkey



4. Switzerland



### 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 3



### 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.

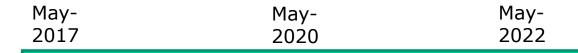
## Main novelties of the new Regulations (2)

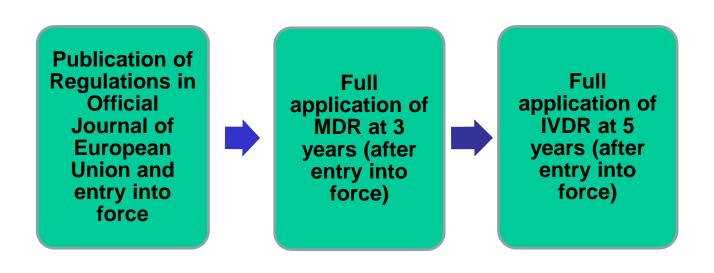
- New classification system for IVDs based on international guidance (80% of IVDs to be assessed by a Notified Body).
- Reinforced designation and oversight processes of notified bodies.
- Clarification of the role and responsibilities of economic operators.
- Establishment of a comprehensive EU database 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.



# **Towards implementation**

# Transitional period







### **COM** implementation priorities (1)

#### Notified Bodies

- ✓ Launch of designation procedure (November 2017)
- √ 52 applications received up to date. Full scope of MDR and IVR covered
- ✓ 4 Notified Bodies designated until Aug 2019. 20 Notified Bodies expected for MDR by the end of 2019

#### Governance

- Setting up of MDCG (November 2017)
- ✓ MDCG technical subgroups (13) operational as from 1<sup>st</sup> Mar 2019
- ✓ Work on 70+ guidance documents ongoing or finalised

#### Scientific structures

- Establishment of expert panels, expert laboratories and reference labs
- ✓ Act on designation of expert panels adopted on 10 Sep 2019

### Design and establishment of the new EUDAMED

- ✓ Plan for implementation of functional specifications (May 2018)
- ✓ Core modules of database to be available by May 2020

### Establishment of UDI system

√ 8 guidelines published, nomenclature selected in Feb 2019, designation of issuing entities finalised in Jun 2019, release of Q/A in Aug 2019

### **COM** implementation priorities (2)

- Mandate for revision of standards (Q4 2019)
- Communication campaign
  - ✓ The new dedicated website and first updated library are live.
  - Release of existing factsheets in all EU languages and some major non-EU languages
  - Release of new factsheets (healthcare professionals and institutions in June 2019)
- Common specifications on devices without medical purpose (expected Q1 2020)
- Common specifications on reprocessing of single-use devices (Q4 2019)

### Planning of activities:

Publication of Commission's rolling plan on DG GROW website

### Useful links

ec.europa.eu

- > growth > sectors
- > register of Commission expert groups > mdcg
- > law > better-regulation > have-your-say

camd-europe.eu

> MDR/IVDR implementation



# Thank you for your attention!

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Health Technology and Cosmetics