MedTech Europe
from diagnosis to cure

Industry Perspective on the current Implementation Status of the MDR

Swedish MedTech Regulatory Summit

20 February 2020, Stockholm

Merlin Rietschel, Senior Manager Regulations & Industrial Policy

1

About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

MedTech Europe
from diagnosis to cure

OUR MEMBERS

130+ multinational corporations*

*medical devices, diagnostics and digital health

50+ medical technology associations

MedTech Europe
from diagnosis to cure

2

Today's agenda

- MDR implementation: where do we stand
- 3 months until MDR Date of Application: A call for action

MedTech Europe
from diagnosis to cure

3

Critical Infrastructure Building Blocks: State of Play

Notified Bodies	**11 out of approx. 43 applicants** are available
(Quality) Guidance	**Approx. 40** are done, but **approx. 40 more are** **still to do**
Acts	**3** Implementing Acts published, **at least 18 total are needed**
Expert panels	**None yet**, and they are not expected until **approx. May 2020**
Common specifications	**None yet**, though the 1st one (on **reprocessing**) is 'coming soon'

MedTech Europe
from diagnosis to cure

4

Recent European Commission and MDCG Activities

27 September: MDCG 2019-9: Guidance on the Summary of Safety and Clinical Performance
30 September: Expert Panels: Call for Expressions of Interest
30 September: Manufacturer Incident Report (MIR) Form: Version 7.2 of the Reporting Template
4 October: MDCG 2019-10: Guidance on the Validity of Certificates Issued under the (AI)MDD
11 October: MDCG 2019-11: Guidance on Qualification and Classification of Software
17 October: MDCG 2019-12: Designating Authority's Final Assessment Form: Key Information
17 October: MDCG 2019-6: Version 2 of the Q&A on Requirements Relating to Notified Bodies
4 December: Unique Device Identification: Formats for HRI, AIDC and Basic UDI-DI
11 December: MDCG 2019-13: Guidance on Sampling of Class IIa/IIb Technical Documentation
11 December: MDCG 2019-14: Exploratory Note on MDR Codes
17 December: MDCG 2019-15: Guidance Notes for Manufacturers of Class I Medical Devices
7 January: MDCG 2019-16: Guidance on Cybersecurity for Medical Devices
10 January: Nomenclature: Notes on the Italian CND and the new European MD Nomenclature

MedTech Europe
from diagnosis to cure

5

MDR Guidance: What's Still to Come?

Ongoing guidance development within MDCG Subgroups – December 2019*

*This is not an exhaustive list of ongoing work performed by MDCG subgroups

Scope	Group Deliverables	Consult prior to MDCG**	Planned MDCG Endorsement	Additional Comments
** Stakeholders are observers in 11 MDCG subgroups and are consulted on a regular basis; further to that other MDCG subgroups are consulted as indicated				
1. Notified Bodies Oversight (NBO)[1]				
MDR + IVDR	*Q&A on Notified bodies –new questions to be added to the document already published*		2020	
MDR + IVDR	*Sampling of devices on a representative basis*	IVD, UDI, Nomenclature, CIE	2019	
MDR + IVDR	*Explanatory note on codes*	IVD	2019	
MDR + IVDR	*Batch verification on class D IVDs*	IVD	TBD	
MDR+IVDR	*Significant changes*	TBD	2020	Task force to be set up
MDR	*Applicability of clinical evaluation consultation procedure*	CIE	TBD	Kick off meeting of the TF on 13/09/2019
2. Standards				

Click here for the **Commission's** Plans for Future Guidance

(last updated: 20 December)

MedTech Europe
from diagnosis to cure

6

Notified Bodies: Capacity vs. Workload

Before 2012	Today		Applied for new 'Notified Body' designation	Notified in NANDO so far	By May 2020
90	56	MDD AIMDD MDR	~43*	11	?

Only about ~15-20 Notified Bodies are expected to be available by May 2020*

Is this enough?

**Numbers given are approximation based on European Commission data and are subject to change.*
IVD Regulation figures are not included in this slide. Data from 14 February 2020

7

NB Designation under IVDR/MDR: State of Play* *(14 February 2020)*

Stages of the NB designation procedure	(1) Complete applications received by DG SANTE	(2) Pre-assessment/ Off-site activities *e.g. Designating Authority Preliminary Assessment Report*	(3) On-site assessments *Audits by Joint Assessment Team (JAT)*	(4) Post on-site assessments *CAPA plans*	(5) Final Designating Steps *e.g. JAT final opinion, MDCG Recommendations*	Notifications published in NANDO
Total	**54** *~45 Notified Bodies in total*	**49** *~90% of applications*	***45* completed** +4 pending *20 CAPA plans to be submitted*	**24** *3 CAPA plans JAT rev. pending +21 CAPA plans JAT reviewed*	*8 DA final reports pending*	**14****
IVDR	**11** *50% of IVDD designated NB*	**9**	**7** *+2 pending*	**4**	**0**	**3** DEKRA DE, BSI UK, BSI NL
MDR	**43** *86% of MDD designated NB*	**40**	**38** *+2 pending*	**20**	**1**	**11** BSI UK, TÜV SÜD, DEKRA DE, IMQ, TÜV Rheinland, DARE!!, BSI NL, DEKRA NL, MedCert GmbH, DNV Presafe, NSAI

*Information based on Team-NB and European Commission information
Scope coverage (NANDO): overall, the entirety of MD and IVD codes

** By 1Q2020: European Commission forecasts more NB designations (IVDR and MDR)

MedTech Europe
from diagnosis to cure

8

8

Delegated and Implementing Acts

- **Standardisation mandate** (*new target for adoption : Q1 2020*) ← *delayed again*
- **Common specifications on reprocessing and reuse of single-use MDs** (*new target for adoption: Q1 2020*) ← *delayed by 1 quarter*
- **Revision of the e-IFU Regulation 207/2012** (*target for adoption: Q1 2020?*)
- **Eudamed** (*new target for adoption: Q1-Q2 2020*) ← *delayed by 1-2 quarters*
- **Common Specifications on MDs without an intended medical purpose** (*new target for adoption: Q2 2020*) ← *delayed by 1 quarter*
- **Expert panel fees** (*new target for adoption: Q4 2020*) ← *delayed by 1 year*
- **Expert laboratories** (target for adoption: '*not before 2020*') ← *not an MDCG priority*

DELAYS ACROSS THE BOARD

- Common specifications for Class D (high-risk) IVDs (*target for adoption: Q1 2020*)
- EU reference laboratories for IVDs (target for adoption: *Q1+Q2 2020*)

MedTech Europe
from diagnosis to cure

Eudamed Database: Delayed until May 2022 (confirmed in late October)

What is the state of play of the implementation of EUDAMED?

- The Commission is working on the implementation of the new EUDAMED database, which will improve transparency and coordination of information regarding medical devices available on the EU market.
- It will contain different modules on actors, UDI & devices, notified bodies & certificates, vigilance, clinical investigations and performance studies and market surveillance.
- The Commission concluded that it will only be possible to make EUDAMED operational once the entire system and its different modules have achieved full functionality and have been subject to an independent audit. Therefore EUDAMED's launch will be done together for medical and in-vitro medical devices, at the original date foreseen for in-vitro medical devices i.e. May 2022.
- The date of application of the MDR remains May 2020.

Source: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en

MedTech Europe
from diagnosis to cure

Eudamed Delay – Plea for Harmonized approach

Joint industry statement
Concerns about the delay of EUDAMED implementation

The European Commission made the official announcement that the implementation of the European Database for Medical Devices (EUDAMED) is delayed by two years. As EUDAMED is

We strongly recommend to the European Commission and member states to align as much as possible at European level and avoid national fragmentation. Information to be provided in national databases should be limited to what is foreseen in the Medical Device Directives.

11

MedTech Europe from diagnosis to cure

11

MDR: 96 Days Left until 26 May 2020

12

MedTech Europe from diagnosis to cure

12

EU Health Ministers: Need for MDR readiness check

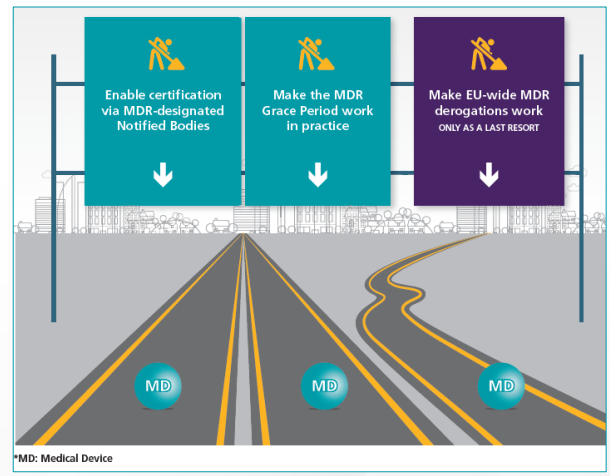
- **MDR** was discussed at the EU 'EPSCO' Council on 9 December 2019.
- Implementation challenges flagged by Health Ministers include Notified Body availability and the delay of the Eudamed database to May 2022.
- **Sweden and Ireland** in particular called for an **implementation readiness check in early 2020**
  - This was well-received and openly supported at the meeting by 21* Ministers of Health
  - MDR Readiness Check: a job led by the national Competent Authorities in the Medical Devices Coordination Group (MDCG).

Country delegations from Bulgaria, Croatia, Finland, Greece, Poland, Romania and the UK did not speak

MedTech Europe
from diagnosis to cure

MDR Priorities in the final 100 days

3 Ways to Keep Devices Available to Patients after 26 May 2020

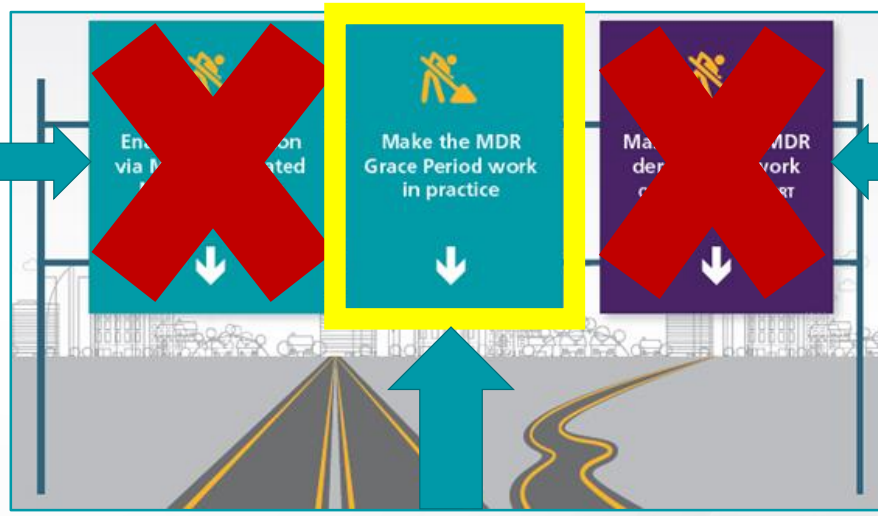


Document publicly-available here: https://www.medtecheurope.org/resource-library/implementation-status-of-the-mdr/

MedTech Europe
from diagnosis to cure

MDR Priorities in the final 100 days

3 Ways to Keep Devices Available to Patients after 26 May 2020



IDEAL…
BUT TOO LATE TO BE A TRUE 'MAY 2020' SOLUTION!

WILL BE NEEDED…
BUT TOO RISKY AND COMPLEX TO RELY ON!

THE MOST FEASIBLE ROUTE
(AND THUS, OUR PRIORITY!)

MedTech Europe
from diagnosis to cure

Enable certification via MDR-designated NBs

CHALLENGES

- Severe lack of NB capacity: low number, certification timelines, workload
- Lack of expert panels: MDR certification inaccessible to various (innovative) MD
- Lack of needed Delegated and Implementing Acts
- Lack of needed EU Guidance
- *De facto* orphaned devices: overworked NBs cannot accept new customers
- Innovation: no spare capacity to assess

PROPOSED SOLUTIONS

- Designate and notify Notified Bodies to the MDR faster; certify QMS timely
- Rapidly establish the panels
- Publish the most needed Acts as soon as possible
- Publish good-quality guidance in the most urgent areas – e.g., clinical evidence requirements

→ If challenges unaddressed, no MDR certification by 26 May 2020. Medical devices **need instead to use one of the two other ways.**

MedTech Europe
from diagnosis to cure

Make EU-wide derogations work - Art. 59(3)

CHALLENGES

- Scope: only intended to address 'exceptional' public health situations
- Process: EU-wide derogation vs. national derogation (fragmentation)
- Timing: granted for only a few weeks
- International dimension: CE marking to keep devices available to patients outside EU

PROPOSED SOLUTIONS

- Make EU derogations a systemic solution: multiple categories from multiple manufacturers
- Publish harmonized procedures, minimize administrative burden
- Allow EU-wide derogations to remain valid for as long as needed
- Confirm unequivocally that theCE marking may be affixed to devices

➡ Need of a significant rethink of the derogation process: difficult to be achieved before 26 May 2020, ***it is critical to make the two other ways to (re-)certify existing and innovative products work, so that devices do not need derogations in the first place.***

17

MedTech Europe
from diagnosis to cure

17

Second MDR Corrigendum

= Enlargement of the MDR 'Grace Period' that lasts until May 2024

Devices *already* eligible for the Grace Period

Products needing Notified Body certification under the old Directives because they were classified as:

- Class III, *e.g.*, **pacemakers**
- Class IIb, *e.g.*, **blood bags**
- Class IIa, *e.g.*, **x-ray machines**
- Class I *sterile*, *e.g.*, **colostomy bags**
- Class I *with a measuring function*, *e.g.*, **thermometers**

Devices *becoming* eligible for the Grace Period

Products that were *Class I self-certified* under the old Directives but need Notified Body certification for the first time under the MDR:

- Reusable surgical instruments, e.g., **scalpels, scissors, forceps, drill bits**
- Devices containing nanomaterials, e.g., **dental impression materials**
- Software, e.g., **software for dental imaging**
- Substance-based devices, e.g., **saline solutions for nasal cleaning**

18

MedTech Europe
from diagnosis to cure

18

Make the MDR Grace Period work in practice

CHALLENGES

- Lack of Notified Body capacity: delays in files, many assessments unfinished by May 2020.
- Lack of EU guidance on 'significant changes': renewed certificates risk of losing validity
- Some NBs are mixing certification requirements of the MDD/AIMDD and future MDR

PROPOSED SOLUTIONS

- Until 26 May 2020 inclusive, NBs:
  (1) continue accepting files for renewal
  (2) review them faster and
  (3) issue CE certificates for all submissions made
- Urgently publish EU-level guidance, to interpret the term 'significant'
- EU-level statement to clarify situation
- Urgently provide guidance and clarity for cases where Notified Bodies have turned down files under GP

➡ In practice 'Grace Period' is currently difficult to apply. A very significant number of devices may only remain available to patients via EU-wide derogations.

MedTech Europe
from diagnosis to cure

MDR: Some Recent MedTech Europe Outreach

(throughout January & February): Various meetings with Member States: Belgium, Czechia, Denmark, France, Germany, Hungary, Ireland, Luxembourg, Poland, the Slovak Republic, Sweden and the UK

29 and 30 January: High-level meetings with new EU Commission, DG SANTE Deputy Director-General (Martin Seychell) and new Head of Unit of SANTE.B6 – Medical Devices (Anna-Eva Ampelas)

CAMD
Competent Authorities for Medical Devices

4 February: Meeting with Competent Authorities for Medical Devices Executive Group Chair (Helena Dzojic, Swedish Medical Products Agency)

12 February: Meeting with Andrzej Rys, European Commission Director responsible for DG SANTE's 'B' units, i.e., health systems, medical products and innovation

MedTech Europe
from diagnosis to cure

Some final thoughts

To Industry

- **Stay vigilant!** These **final weeks are going to be very tight**, and much could still change
- **Speak up!** If you experience challenges, **engage your Ministry of Health & competent authority** to ensure your voice is heard

To European Commission and Member States

- **Communicate!** We need to know **what steps you will take if the Regulations aren't successfully implemented on-time**

21

Tack så mycket!

m.rietschel@medtecheurope.org

www.medtecheurope.org

MedTech Europe
from diagnosis to cure

22