

Industry Perspective on the Implementation Status of the MDR/IVDR

07 June 2019



MedTech Europe
from diagnosis to cure

1 In less than 1 year the new Medical Device Regulation will enter into full effect. Soon after, so too will the *In Vitro* Diagnostic Medical Device Regulation.

2 The Medical Device Industry in Europe is *deeply concerned* that the new regulatory system will not be ready on time.

3 If the system is not ready *well ahead* of the deadline of May 2020, it puts at risk the continued supply of life-saving and life-enhancing technologies.

4 European Commission and Member States *need to move faster* in order to get the new system ready on time. We must not put patients at risk, nor negatively impact healthcare systems.

5 We recognize the shift to a new system is a major task. This presentation seeks to clearly lay out the fundamental areas that need addressing with urgency.

This presentation

1 Context

2 Urgency is increasing

3 7 critical areas

Notified Bodies

Re-certification

Eudamed

(Quality) Guidance

Scientific Bodies

Acts

Harmonised Standards

Context

What is at stake?

Patient care



Product supply to hospitals



European innovation ecosystem



Small and medium-sized enterprises



What needs to happen?

Industry has always supported the new system, and continues to do so

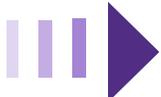


Regulators need to ensure that products can get approved on time



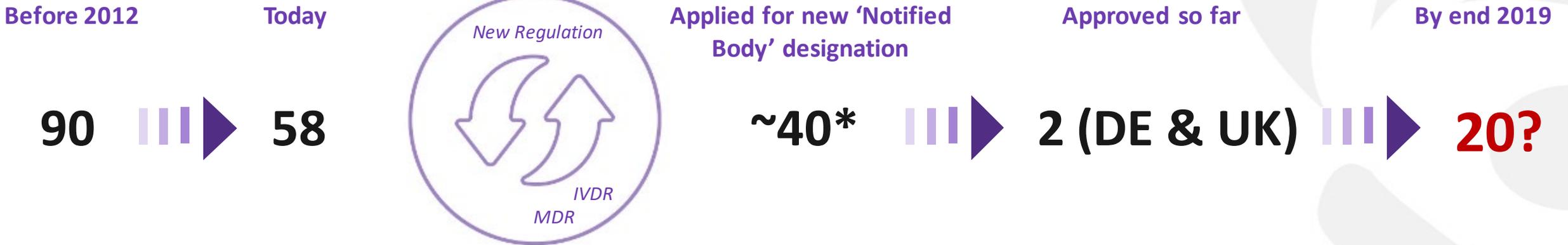
Products cannot be submitted for review without critical infrastructure, which is not yet in place

Critical infrastructure building blocks: Where we stand with 1 year to go

Notified Bodies		2 are notified, out of nearly 60 (one of them being BSI UK)
(Quality) Guidance		Some are done, most are still to do
EU reference laboratories		None yet
Acts		2 Implementing Acts published, at least 16 more are needed
Expert panels		None yet
Common specifications		None yet

Can this gap be closed early enough BEFORE May 26, 2020?

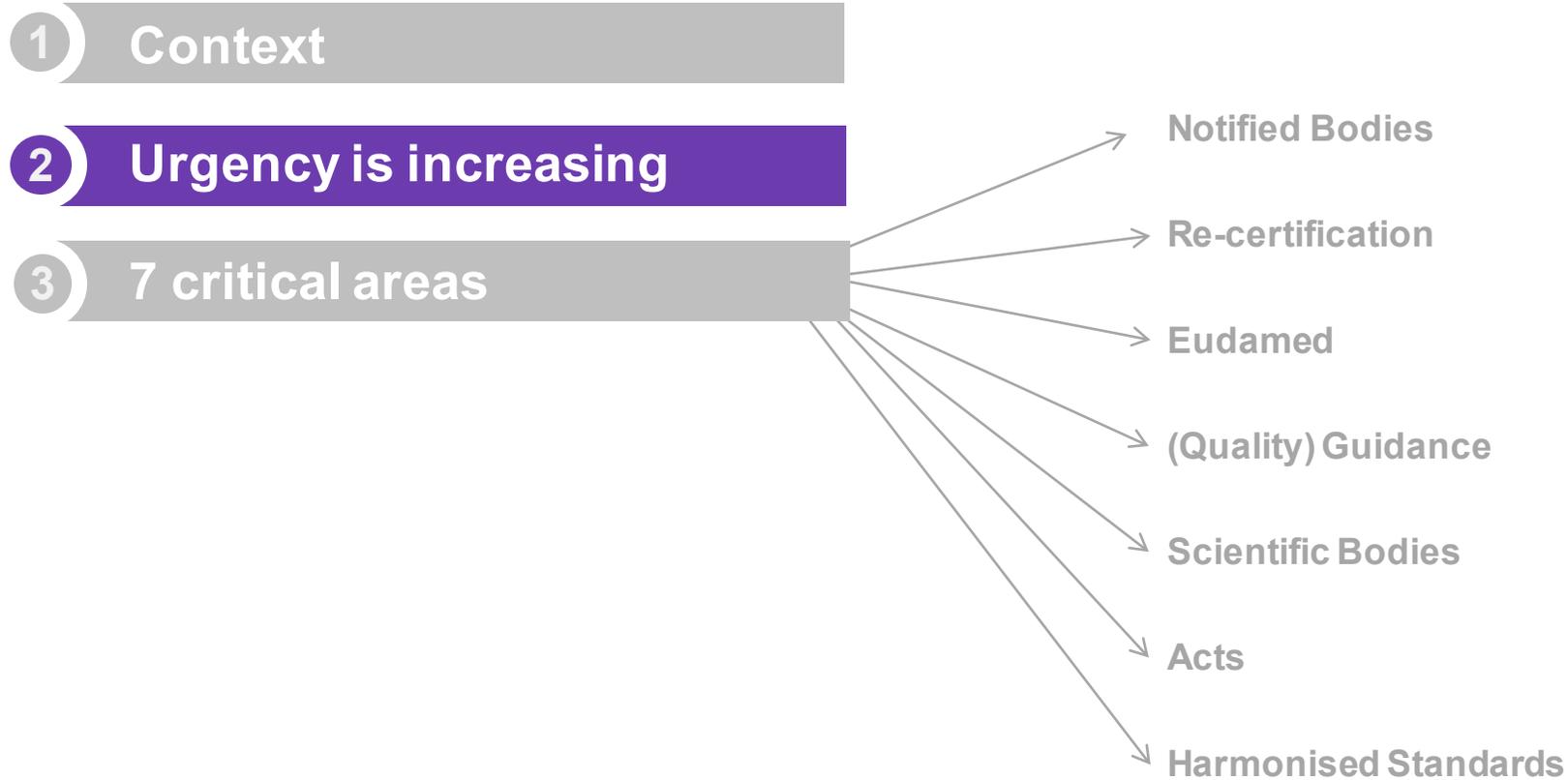
Notified Bodies: The numbers



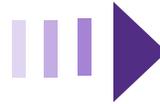
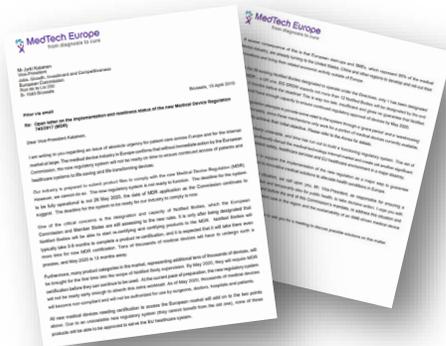
Only about 20 Notified Bodies are expected to be available by the end of 2019*. Is this enough?

*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 27 May 2019.

This presentation

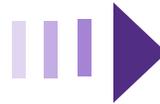


Industry has expressed concerns in numerous ways this year



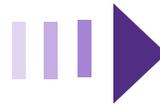
Link [HERE](#)

Concerns expressed and immediate action urged at the highest institutional level (Commission Vice-President and national Ministers of Health)



Link [HERE](#)

Joint medical technology community statement expressing urgent concerns



Link [HERE](#)

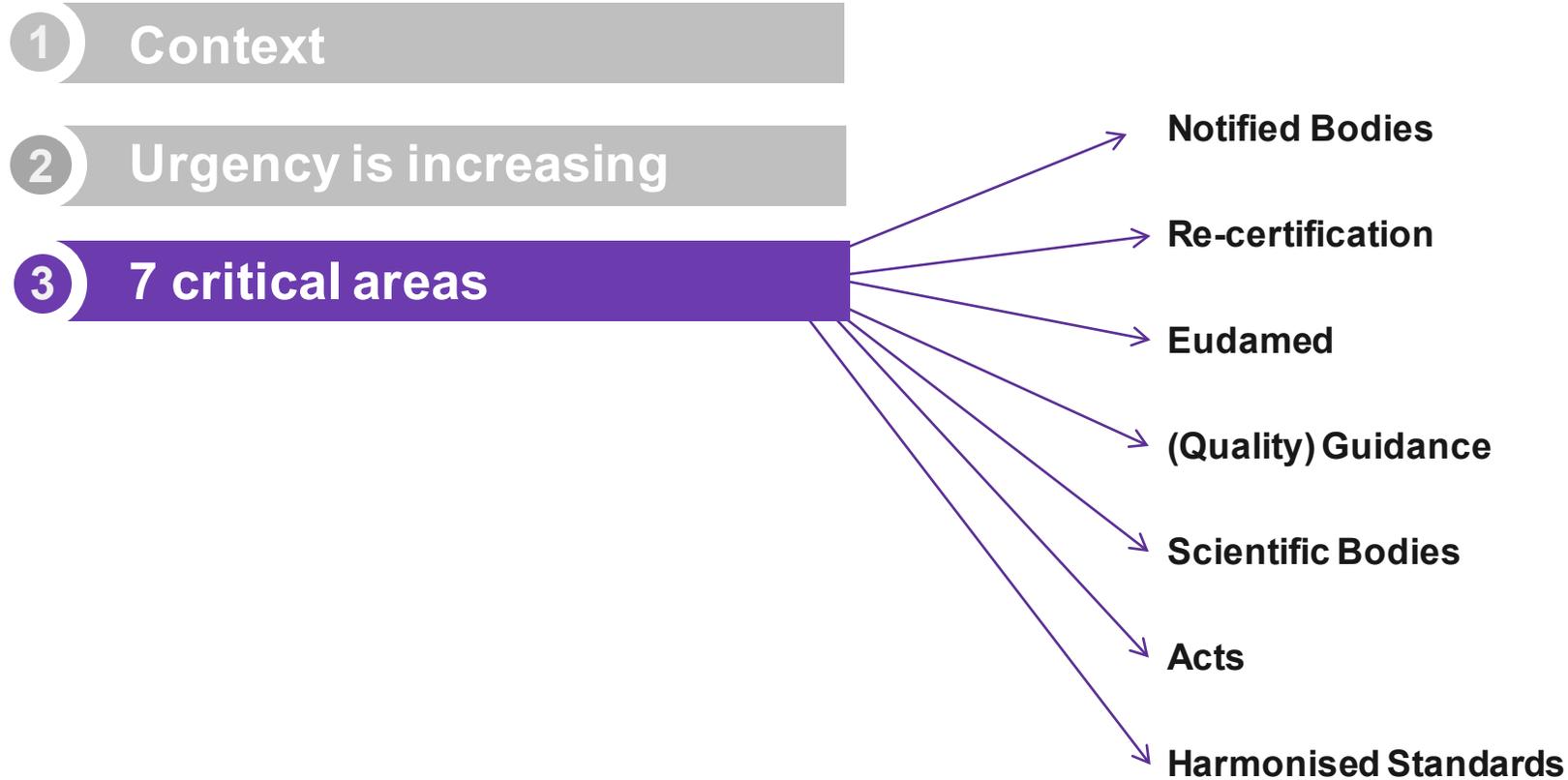
Visualisation of the problem through simple animated videos

- 1 **Notified Bodies:** Designate them faster
- 2 **Re-certification:** Ensure the procedure works for all products
- 3 **Eudamed:** Deploy the new database with workable IT specifications and implementation timelines
- 4 **(Quality) Guidance:** Publish it in the most urgent areas
- 5 **Scientific Bodies:** Rapidly establish the new expert panels and EU reference laboratories
- 6 **Delegated and Implementing Acts:** Publish the most-needed ones, including certain 'system-critical' common specifications
- 7 **Harmonised Standards:** Ensure they are available in the highest-priority areas first



Solution-focused 7 point plan for accelerating implementation (*this* document)

This presentation



Our Call to Action for Member States

Implement the new
regulatory system
faster and with
more efficiency

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Context

- **Only 2 Notified Bodies (NBs) are currently available.** 26 May 2020 is less than 12 months away
- Too few NBs are in the pipeline. It currently takes around 18 months to designate a new body. The designation **process is going too slowly** at this pace to have enough ready in time
- Industry is **already experiencing certification bottlenecks/delays** under the former Directives

Timing



MDR

European solutions are needed ASAP to avoid market disruption



IVDR

Designations need to start in earnest from mid-2019 onwards

Solution

Designate Notified Bodies faster

- **Acknowledge that we are not on-track**, and prepare for future insufficient NB availability
- Develop and communicate a coordinated, EU-wide solution that ensures that **manufacturers can continue CE marking**, even if they temporarily become ‘orphans’ (i.e., if they lose their NB)
- **Accelerate NB designation** by removing as much bureaucracy from the process as possible



1. **Staffing:** Designate the NB, and let the NB start working, while extra staff are being recruited
2. **Auditing:** Consider the NB's past track record under the former Directives, instead of re-assessing *everything* from A to Z
3. **Notification:** Minimise the 42-day 'delay' before notification is posted to the NANDO database

Context

- Specific families of existing products are **at special risk of becoming unavailable**:
 1. Products **ineligible** for the 'Grace Period' that extends until May 2024, e.g., 'Class I reusable surgical instruments' like *scalpels, scissors, forceps, drill bits*, etc.
 2. Products eligible for the grace period but unable to use it due to **insufficient NB capacity**

Timing



Without a clear, actionable plan in place by **August 2019** there is a serious risk that certain products become unavailable

Solution

Ensure the procedure works for all products

- Put in place a **staged (re-)certification sequence** for NBs to follow, e.g., giving priority to product families which cannot use the 'Grace Period'
- Agree **workable re-certification timelines** and processes for existing 'combination products,' i.e., medical devices that incorporate ancillary medicinal substances

Context

- Without a fully functional database, the **Regulations' benefits would be severely reduced**
- **Some parts of the database are encountering delays**, e.g., due to debates about whether existing devices should be (re-)registered in Eudamed...and other parts are being rushed
- Manufacturers need **sufficient time** to adapt their IT systems to Eudamed's technical specs

Timing

-  • **Actor registration module:** Single Registration Numbers critical, needs immediate deployment
-  • **UDI, device and certificate registration modules:** 2nd priority. Deploy them ASAP
-  • **Vigilance and clinical modules:** Ensure 18 months minimum before 'go live' date

Solution

Deploy Eudamed with workable IT specs and implementation timelines

- **Rapidly define and validate all Eudamed modules** needed by May 2020
- If this cannot be achieved with clear timelines, **publish contingency guidance** to inform stakeholders how to proceed while Eudamed is still being built
- Only make the modules **compulsory 18 months or more after publishing stable IT specs**
- Prioritise on delivering a **fully functional database for IVDR/MDR-certified products**

Context

- **Most** guidance documents are still to be published
- Some guidance documents are **as important as the ‘core infrastructure’** supporting IVDR/MDR implementation

Timing



MDR

August 2019 is the latest timing that will realistically allow a smooth transition



IVDR

Guidance on classification and sampling of Class B & C needed **Q3 2019**. Everything else should be published by **May 2020**

Solution

Publish it in the most urgent areas

- **MDR:** Publish as a priority guidance on software classification, Eudamed and UDI, transitional provisions, post-market surveillance (PMS), and on Article 61.6 ('sufficient clinical data')
- **IVDR:** Progress urgently with guidance on IVD classification, performance evaluation, conformity assessment (including sampling of Class B & C), PMS, companion diagnostics and software-specific aspects

Context

- These bodies must be **set up for the very first time**, and thus constitute ‘new territory’
- They are **required for IVDR/MDR certification of innovative, highest-risk devices**

Timing



MDR

Expert panels for **all therapeutic areas** are need to be set up and running **end 2019** to ensure no delays



IVDR

May 2020 is the latest by which fully functional EU reference laboratories, expert panels and common specifications are needed

Solution

Rapidly establish the expert panels and EU reference labs

- Establish these bodies **while the needed Implementing Acts are being adopted**, e.g., Implementing Acts specifying the bodies' roles and fees
- Ensure that these bodies function as efficiently as possible, with **clear, strict scopes**
- For expert panels specifically: **Clarify if certain branches of medicines will take priority over others**, or whether all therapeutic/diagnostic areas are of equal priority

Context

- Even the most **'mandatory' Acts** are only starting to be published into Year #3 of transition
- Implementing Acts laying down **common specifications (CS)** are crucial for the conformity of some devices, e.g., Class D IVDs, and 'aesthetic' medical devices listed in MDR Annex XVI
- **Manufacturers need many months to adapt** to the changes these Acts will bring

Timing

 • Horizontal Acts – e.g., roles and fees for expert panels – needed no later than August 2019

 **MDR**
CS on Annex XVI products needed no later than **August 2019**

 **IVDR**
CS published by **end 2019 to avoid delays**

Solution

Publish the most-needed acts, including certain 'system critical' common specifications

- **Publish clear, ambitious target deadlines** for developing and publishing all foreseen Acts
- **Consider 'upgrading' the priority of certain Acts** that are not currently in the Rolling Plan, e.g., the Act on free sale certificates, or the Act on implant card exemptions
- **Expedite as much as possible the most-needed CS**, e.g. ex-IVDD CTS → IVDR CS

Context

- Harmonised standards **ensure products are safe and work as intended**
- They contribute to consistent conformity assessments & have been **key compliance tools**
- They are currently on-track to be absent from the IVDR/MDR until (potentially several) years from now. This leads to uncertainty about how to proceed.

Timing

- **May 2020** is ideal, but no later than May 2021

Solution

Ensure they are available in the highest-priority areas first

- Prioritise the harmonization of standards in **areas of most horizontal importance**, e.g., in areas like symbols, labelling, risk management, and good clinical (study) practice.
- **Ensure all stakeholders including CEN/CENELEC work together**, time is running out

Summary

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Last requests

To Industry

- **Stay vigilant!** These final months 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

- **Please speed up!** It will soon be too late to deliver the regulatory system's most critical infrastructure. **Patient care is at stake**
- **Communicate!** We need to know **what steps you will take if the Regulations aren't successfully implemented on-time**



Thank you
for your time

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