EU Medical Devices Regulation 745/2017

Industry Perspective on the Implementation Status

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MedTech Europe

from diagnosis to cur

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.**

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

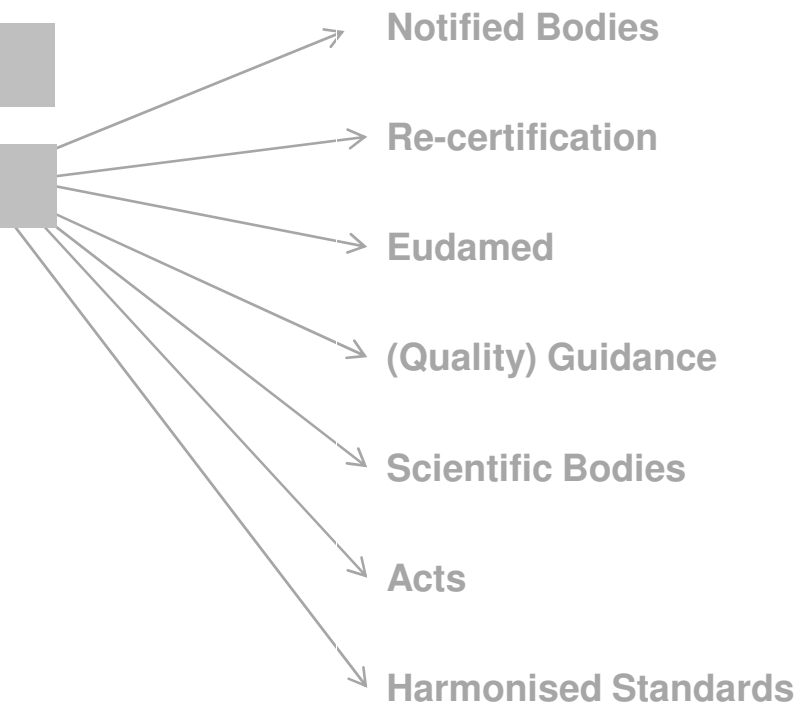
3 If the system is not ready *well ahead* of the deadline of May 2020, it puts at risk the continued supply of life-saving and life-enhancing technologies.

4 European Commission and Member States *need to mov 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.**

his presentation

1. Context
2. Urgency is increasing
3. 7 critical areas



ontext

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

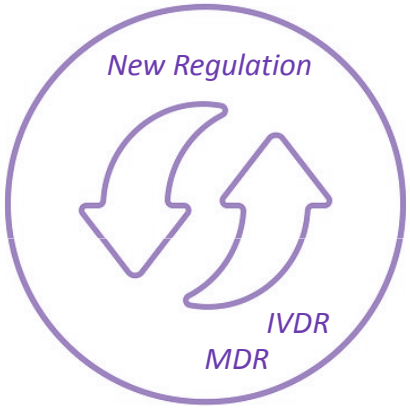
Critical infrastructure building blocks: Where we stand with 1 year to go

Notified Bodies	2 are notified, **out of nearly 60 (one of them being BSI *U***
(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 need**
Expert panels	**None yet**
Common specifications	**None yet**

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

Notified Bodies: The numbers

2012 → Today: **58**



Applied for new 'Notified Body' designation: **~40***

Approved so far: **2 (DE & UK)**

By end 2: **20**

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

rs given are approximation based on European Commission data and are subject to change.
gulation figures are not included in this slide. Data from 27 May 2019.

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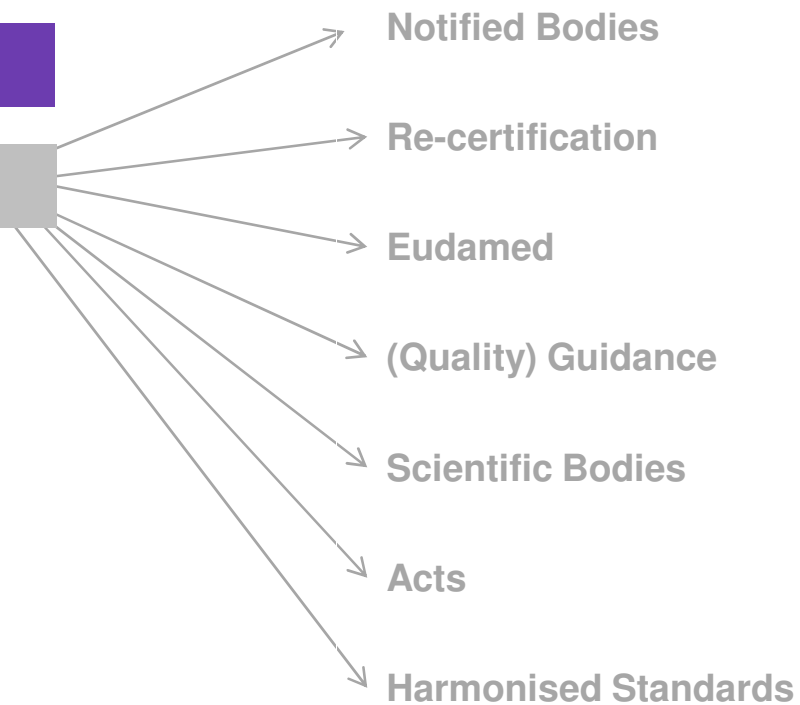
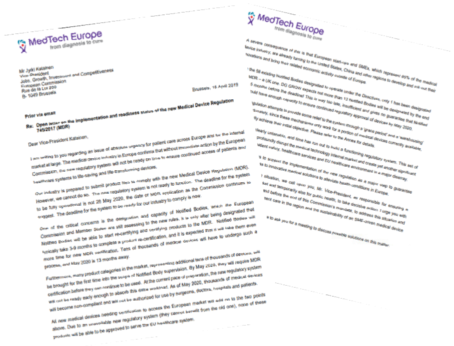


ndustry has expressed concerns in numerous ways this year



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

Link HERE

AESGP eurom FIDE GIRP MedTech Europe

Healthcare systems across Europe in need of accelerated implementation of the Medical Device Regulation

We, the undersigned, are committed to regulations that will ensure patient safety and continued access to medical devices for patients, healthcare professionals and healthcare systems in Europe.

On 26 May 2020, less than one year from now, the new Regulation for Medical Devices will enter into full effect. However, the new regulatory system will need to be fully functional months before this deadline, in order to enable the thousands of medical devices currently on the market to go through a mandatory 3-9 months re-certification process.

The timely functionality of the system is critical to guarantee the continued supply of devices to health institutions. But as of today, achieving this is very unlikely thereby putting patient care across Europe at risk.

Joint medical technology community statement expressing urgent concer

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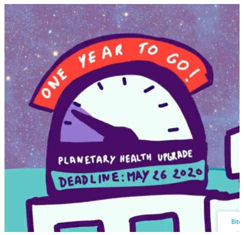

Visualisation of the problem through simple animated videos

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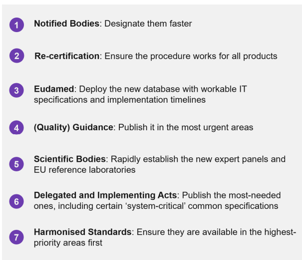

1. **Notified Bodies**: Designate them faster
2. **Re-certification**: Ensure the procedure works for all products
3. **Eudamed**: Deploy the new database with workable IT specifications and implementation timelines
4. **(Quality) Guidance**: Publish it in the most urgent areas
5. **Scientific Bodies**: 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

Link HERE

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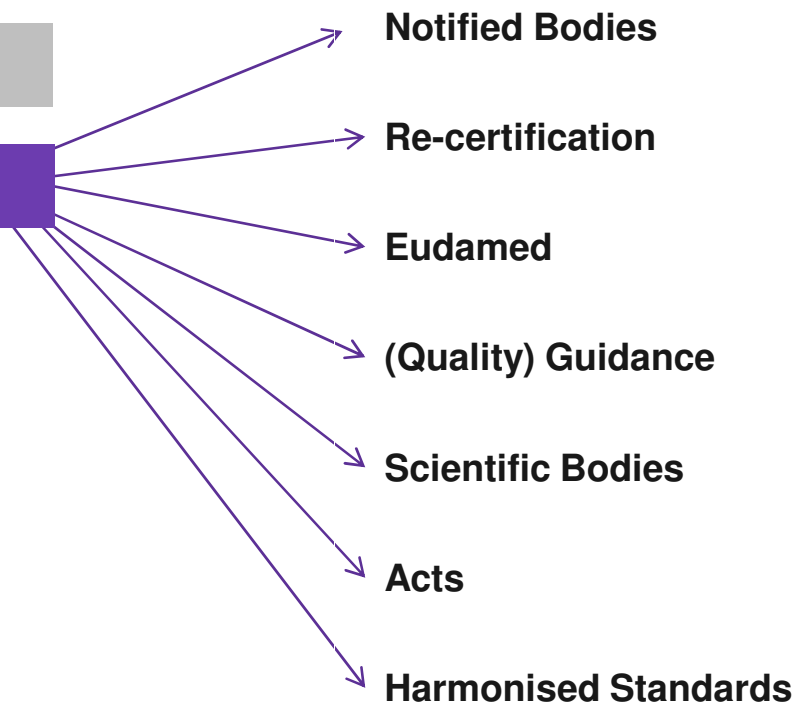

ur Call to Action
r Member States

plement the new
gulatory system
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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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