MedTech Europe
from diagnosis to cure

New Regulations:
Patient and Health Systems implications

Industry's point of view

Dario Pirovano, Senior Regulatory Adviser
MedTech Europe

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Hotel TRYP Lisboa Aeroporto

A Modernised, Strengthened System

High Risk Devices

- **Up-classification**, e.g., of joint replacements, or devices in contact with the spinal column or central circulatory system
- **New 'scrutiny' process:** Extra time to market?

Notified Bodies

- **Stricter:** Especially on clinical evidence
- **More consistent and harmonious:** Joint accreditation and supervision by multiple Member States acting together

Clinical Evidence

- **Clinical data**: Greater need for clinical investigations and clinical data transparency
- **Clinical investigations**: Dedicated EU rules

…and many more

- **Eudamed database**: Central data submission at EU level
- **Labelling & Instructions for Use**: Modifications needed
- **Reprocessing of single use devices**: More explicitly regulated

NO GRANDFATHERING…

Why this Overhaul was Needed

1. **To modernize the legislation**, e.g.,
   - Clarify which products are medical devices and their level of risk,
   - Introduce cybersecurity requirements for software/IT infrastructure,
   - Facilitate traceability of devices circulating on the EU market

2. **To increase trust in the EU regulatory system,** e.g.
   - Increase transparency and public information about devices on the market

3. **To strengthen the Notified Body system**, i.e.,
   - Raise the bar for organisations claiming competence to audit/certify devices
   - "*Get rid of the bad apples*" following past experiences with the subpar performance of certain Notified Bodies

INDUSTRY SUPPORTS ALL THIS (and is investing heavily to comply!)

“So what’s the problem?”

1) Key pillars of the new system aren’t ready

2) Time is running out for Notified Bodies to re-assess & re-issue approx. 32,000 certificates

3) Risk of an approaching ‘cliff edge’ for availability of medical devices in Europe

Ongoing Industry Concerns from the Field

Limitations of the Grace Period

- Many product categories are *ineligible*
- NBs lack the *capacity* to do renewals on time
- What is 'appropriate' NB *surveillance* tasks?
- There is still no 'significant change' *guidance*
- What does it mean in practice to apply the *IVDR/MDR* rules on PMS, vigilance, etc.?

NB capacity still critically-low

- Companies are asked to *prioritise* files submitted.
- To assess changes, the NB may need to find the time by *dropping* files already submitted
- 'Non-priority' devices risk becoming unavailable..
- Sampling frequency for Class B/C + IIa/IIb presents considerable *workload* concern

Other challenges

- Increased NB *fees*: Transparency?
- *Inconsistency* between NBs
- Combination products: need to repeat *210-day* consultations?
- Certs for all low risk classes ?

"Innovation Black-Out"

- Huge focus by MDR-designated NBs on (re-) certifying *existing* MDs
- Refusal to assess *new* products
- Some product launches are now starting in *China* or *the US*.
- No Expert Panels = NB refusal to *start* evaluating certain files!

Solutions are needed well BEFORE May 2020/2022

Notified Bodies: The Numbers as of October 2019

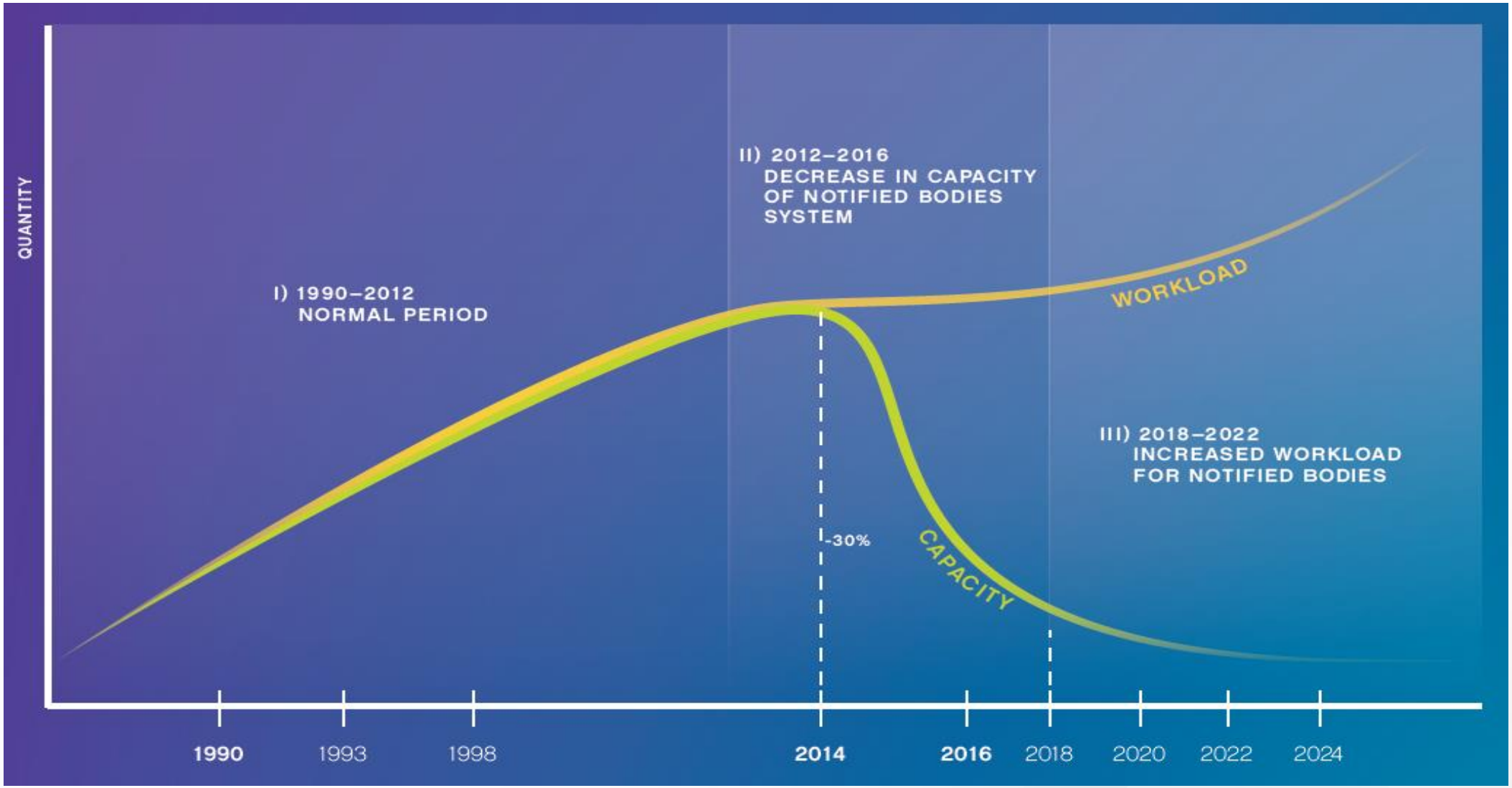
Former Directives	
Before 2012	**Today**
Nearly 90	56 (and decreasing…)

New Regulations	
Applied*	**Passed the Process**
Approximately 40	**5** - MDR 1 - IVDR

By the end of 2019, we expect only 12-15 Notified Bodies will have passed the process

* Note: Numbers given are approximations, based on European Commission data, and are subject to change

Notified Body Capacity vs. Workload vs. TIME



Full chart available here: https://www.medtecheurope.org/wp-content/uploads/2018/10/MTE_NB_Capacity_Gap_Infographic_Oct18-WEB.pdf

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MedTech Europe's Call to European Authorities

Implement the new regulatory system **faster** and with more **efficiency**:

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

…then a great deal is potentially at stake:

<u>But above all</u>

Our <u>common</u> duty to ensure continuity of care to patients!

1. **Device disappearances?**
2. **Device shortages?**
3. **Reduced variety of available devices/suppliers?**
4. **Market consolidation / potential disappearance of SMEs?**
5. **Wards need to restructure/reorganise themselves (or close)?**
6. **Doctors and nurses need to learn to use alternative devices?**
7. **Slower arrival of innovations to the market?**

More Stakeholders are Joining this Conversation!

EFORT Head Office
ZA La Pièce 2
1180 Rolle, Switzerland
Tel +41 21 343 44 00
Fax +41 21 343 44 11
office@efort.org
www.efort.org

Rolle, 28 August 2018

New Medical Devices Regulations (MDR) and In Regulations (IVDR)

EFORT calls upon the European Commission implementation of the new Medical Devices Medical Devices Regulations (IVDR) does n medical devices, which enable the safe t outcomes.

EFORT is the European Federation Traumatology, representing more than heavily on implantable medical devi Examples include fracture fixation de

EFORT believes that robust regula introduction and use of devices stimulating independent overs Registries. Strengthening of th

The MDR and IVDR publish allow new regulatory syste designated, and establish European Commission appropriate infrastructu This includes the esta of common specifica uniformity in the in

EFORT is concerned tha not achieved by the end o this impact on the introduction all devices currently in use will not b withdrawal of implants and devices curr a grace period was sensible, it should mo point at which all necessary infrastructure needed be in place.

TIC COUNCIL

Towards a smooth transition for m

To: Ms Elżbieta Bieńkowska
Commissioner for Internal Market, Industry, Entrepreneurship and SMEs
European Commission

Cc: Mr Carlo Pettinelli, Director for Consumer, Environmental and Health Tec
Mr Salvatore D'Acunto, Head of Unit for Health Technology and Cosmetics

Dear Commissioner Bieńkowska,

The TIC Council, representative of testing inspection and certification (TIC) sector express its concern on the status of the implementation of the new Medical Devices Reg and the In-Vitro Diagnostics Medical Devices Regulation (IVDR).

We are particularly concerned that two years after the entry into force of the two Regulation
1. Essential regulatory infrastructure, such as implementing acts, are still missing.
2. Several guidance documents are still missing or have room for improvement in describin requirements for conformity assessment bodies.
3. The European Database on Medical Devices (EUDAMED) System[1] is not running as planned

The MDR and the IVDR foresee the publication of more than 80 delegated and implementing acts, including Common Technical Specifications of which 18 are mandatory[2]. These acts are necessary for the implementation and unambiguous interpretation of various new and amended requirements.

Moreover, various types of guidelines are still lacking, such as the "MEDDEV documents", Common Technical Specifications as well as interpretative and informative documents, which are necessary for the implementation and unambiguous interpretation of the new and amended requirements. These circumstances cause a high level of uncertainty to our sector, which does not encourage the necessary investment for ensuring the smooth transition to the new Regulations.

We expect that the new product scope and responsibilities, such as the strengthened duties for on-site audits under the upcoming Regulations, will offer opportunities for conformity assessment bodies. Therefore, we expected a higher number of conformity assessment bodies to apply for notification under the new Regulations.

Nevertheless, to live up to the new expectations, conformity assessment bodies need to invest in hiring of additional experts, training, and equipment. The conformity assessment bodies are discouraged to proceed with such investment because of the aforementioned impediments.

EPF European Patients Forum

ESC European Society of Cardiology

Biomedical Alliance in Europe

PATIENTS AND DOCTORS CALL FOR URGENT INVESTMENT TO ENSURE THAT THE EU MEDICAL DEVICES REGULATION IS IMPLEMENTED ON TIME

OPEN LETTER TO EU HEALTH MINISTERS

It is now less than one year to 26 May 2020, when the new EU Regulation on Medical Devices (EU 745/2017) must be applied.

The Regulation mandates stronger safety requirements for high-risk medical devices, greater transparency of clinical evidence, and strengthened post-market surveillance.

Medical devices are vital for the prevention, diagnosis and treatment of disease. The successful implementation of the Regulation is a fundamental priority for patients and healthcare professionals requiring access to safe, innovative and effective technologies.

Progress has been slow. Limited regulatory capacity and manpower threaten the swift and effective implementation of the Regulation. Calls from the European Parliament to ensure that sufficient resources are dedicated within the European Commission have so far been ineffective; the number of dedicated regulatory staff in the Health Technology Unit in DG GROW[1] in Brussels is only 10.

This will be discussed by the Council of the European Union - EPSCO[2] on June 13-14.

Patients and healthcare professionals call jointly for European Union Member States to increase investment urgently, in order not to risk postponing implementation. By freeing up resources and boosting the capacity of the European Commission and national competent authorities it will be positive to speed up the designation of notified bodies, complete implementing legislative acts, ensure a fully functional Eudamed database and introduce the system of expert panels.

A realistic appraisal of progress is essential, and contingency plans must be transparent.

Brussels, 7 June 2019

CED COUNCIL OF EUROPEAN DENTISTS

CED-DOC-2019-027-FIN-E

CED POSITION ON IMPLEMENTATION OF MEDICAL DEVICES REGULATION

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dental practitioners across Europe through 33 national dental associations and chambers in 31 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED key objectives are to promote high standards of oral healthcare and dentistry and effective patient-safety centred professional practice.

Medical Devices Regulation (MDR) 2017/745[1] is an essential piece of legislation for ring high-quality health care and a cornerstone of patient safety across Europe that will plicable in all EU Member States from 26 May 2020.

supports improvements of the system imposed by the new regulation but also shares oncerns in relation to the smooth implementation of the MDR by the relevant date.

ementation of new classification rules for all medical devices;
bility and capacity of Notified Bodies across the system.

veloping both areas have caused deep concerns amongst the profession
f the system for May 2020, and the continued availability and timely
l devices and therefore, optimal patient treatment options.

pretation of the MDR provisions could result in shortages of medical
ealth professionals on a daily basis; some devices might not be
May 2020 if their classification and/or accreditation is delayed.
the provision of health services across the European Union.

entation of the Regulation by May 2020, we call on the
States to provide detailed guidance on the classification
ary systems are ready and the new notification bodies
work by the early autumn of 2019. It is paramount to
oon as possible to ensure full functionality of the new system.

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The EU Commission Acknowledges Some Challenges

- *Factsheet for Healthcare Professionals* ***and Health Institutions*** published on 5 June
- "*In general, no requirements from the Directives have been removed; the Regulations add* ***new ones****.*
- *….these changes could have* ***consequences for the availability*** *of…devices for health institutions...(and) manufacturers may choose to* ***stop the production*** *of certain medical devices…*
- ***…if certain medical devices do not get their certificates on time these products may become temporarily unavailable***."


European Commission

Factsheet for
healthcare professionals and health institutions

This factsheet is aimed at healthcare professionals and health institutions. For a general overview of the impact of the Regulations please refer to the Medical Devices' section on the website of the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW).

The new Medical Devices Regulation (2017/745/EU) (MDR) and the new *In Vitro* Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR), adopted in May 2017, will replace the existing Medical Devices Directive (93/42/EEC) (MDD), the Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD) and the *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) (IVDD).

The publication of the MDR in May 2017 marked the start of a 3 year period of transition from the MDD and the AIMDD.

The publication of the IVDR in May 2017 marked the start of a 5 year period of transition from the IVDD.

MEDICAL DEVICES: CHANGE OF LEGISLATION
What you need to know!

Introduction to the Medical Devices Regulation (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR)

The new Regulations will create a robust, transparent and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access conditions for manufacturers.

In contrast to directives, regulations are directly applicable and do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risk of discrepancies in interpretation across the EU.

…and MOST Importantly… Ministers of Health are now Engaged

- At the initiative of **Germany** and **Ireland**, the MDR transition challenges were discussed at the EU 'EPSCO' Council on Friday 14 June.

- **20 Member States** took the floor to express concerns, particularly regarding *Notified Body availability and capacity*

- The Romanian Presidency concluded the discussion by stressing the point that Member States should **look for European solutions** for a timely MDR implementation.

Council of the European Union

Brussels, 6 June 2019
(OR. en)

Notified Bodies and Capacity Issues

Much of the concern raised to date relates to the availability and capacity of notified bodies for medical devices under the new Regulation. There is undoubtedly huge dedication and commitment from the European Commission and Member States to progress the work on designation. However, based on the number of notified bodies which are expected to be available on time, there will still be significantly fewer notified bodies than currently exist. In addition, data is not available on the capacity these designated bodies will afford the system.

Devices which are certified under the existing legislation can continue to be placed on the EU market under their existing certification up until 2024, however this does not apply for all devices. Specific concerns on the impact of a lack of notified body capacity have frequently been raised in relation to existing devices, which are up-classified or subject to additional regulatory assessments as a result of the new Regulation, for example surgical instruments which are intended to be re-used. The concerns expressed are that these products cannot continue to be placed on the market under their existing Directive certificate up until 2024, like most other existing medical devices and that this will lead to market shortages.

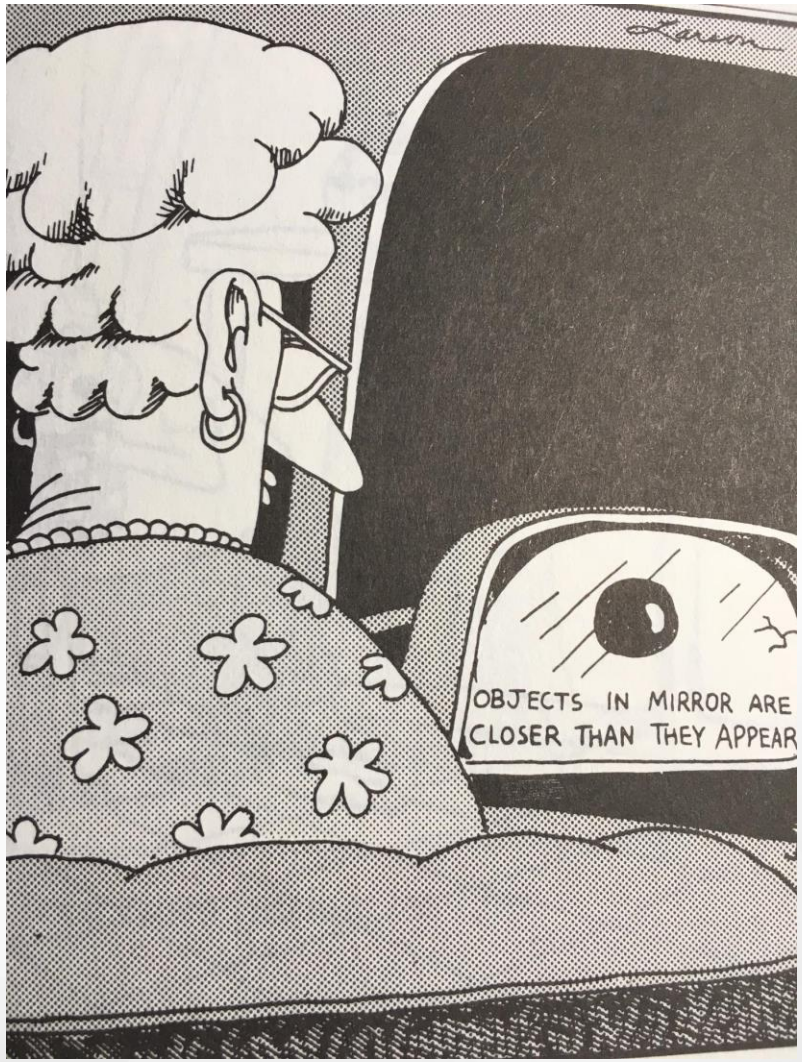
Final Thought: 'National Derogations' as a Solution

- Some Member States **acknowledge** the challenges, but they believe they can keep healthcare-critical devices available via short-term, *national* approvals
- Industry sees such measures as an absolute **last resort**, to only seriously consider if there is genuinely no other way to make the new regulatory system work
- These measures can only work if they are *European* (not national) in nature, and if the following **minimum** criteria are ensured**:**

1. **Timing:** Approvals ('derogations') must be given for sufficiently-long periods
2. **Scope:** Devices must be eligible to receive derogations in groups/categories, and more than just 'healthcare critical' devices must be eligible
3. **Procedure:** Application process needs to be clear, with minimal bureaucracy
4. **International dimension:** It must be possible to keep the CE marking on devices to ensure global acceptance of the derogation and marketability of the products

Take-home Messages

1. **Be aware and alert!**
   - ➢ The Regulation takes effect in 215 days!
   - ➢ There are major transition challenges for which all stakeholders have to prepare
2. **Be vocal!**
   - ➢ Patients, doctors, authorities and industry are all discussing this
3. **Be ambitious!**
   - ➢ We have a shared duty to patients, so let's work together to keep devices available!



Thank you!

Dario Pirovano

d.pirovano@medtecheurope.org

+32 475613457

www.medtecheurope.org

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