MedTech Europe
from diagnosis to cure

EU IVDR/MDR Implementation

Quarterly update from MedTech Europe

Webinar

18 January 2021

Welcome to Europe!

Today's Agenda

1. **Notified Body audits**: *Oliver Bisazza*
2. **(*voluntary*) EUDAMED registration of Economic Operators**: *Oliver Bisazza*
3. **EU-Switzerland Mutual Recognition Agreement**: *Jesus Rueda*
4. **EU-Turkey Customs Union**: *Jesus Rueda*

Remember

- There will be question-time at the end
- Feel free to reach out afterwards!

Part 1

Notified Body Audits under the EU IVD and Medical Devices Regulations (IVDR/MDR)

Notified Bodies: The Numbers as of January 2021

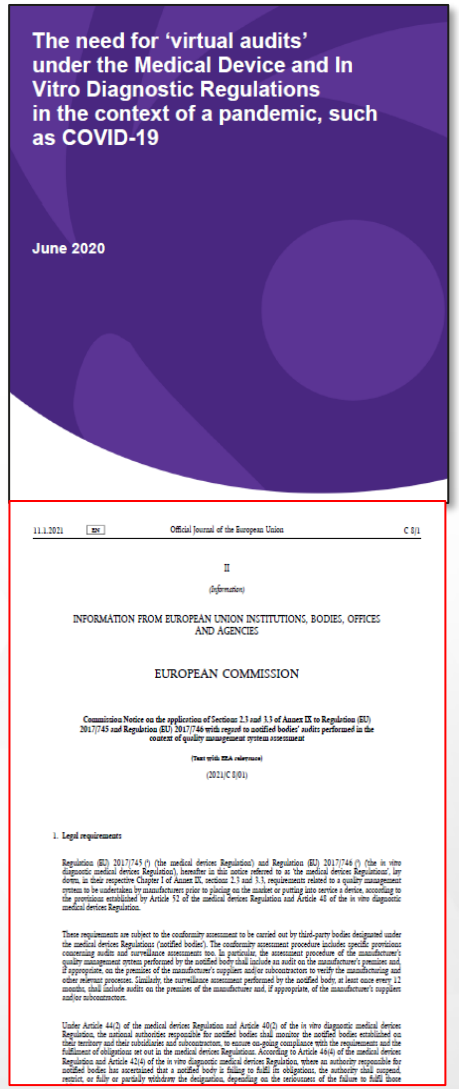
Directives	
Before 2012	**Today**
Nearly 90	52

Regulations	
Applied*	**Designated**
50 under MDR (~90%) 16 under IVDR (~90%)	18 MDR 4 IVDR

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

‘Virtual’ Notified Body Audits under the IVDR/MDR

- **As per IVDR/MDR, on-site audits at the manufacturer’s premises are needed** to support CE marking of devices
- **Extensive industry and Notified Body outreach** throughout 2020 to advocate **virtual audits** to keep moving forward with IVDR/MDR certifications in a COVID-19 travel restrictions context
- **State of play:**
  - **European Commission published Notice** (11 January 2021): Although not legally binding, this publication seems to give a ‘nod’ to Member States, i.e., to tolerate virtual Notified Body audits under specific circumstances
  - **EU Member States:** Practical application of the Notice still to be discussed and if possible aligned
- **European Commission Notice:** significant step, **welcomed** by vast majority of EU Member States, but **open questions remain**



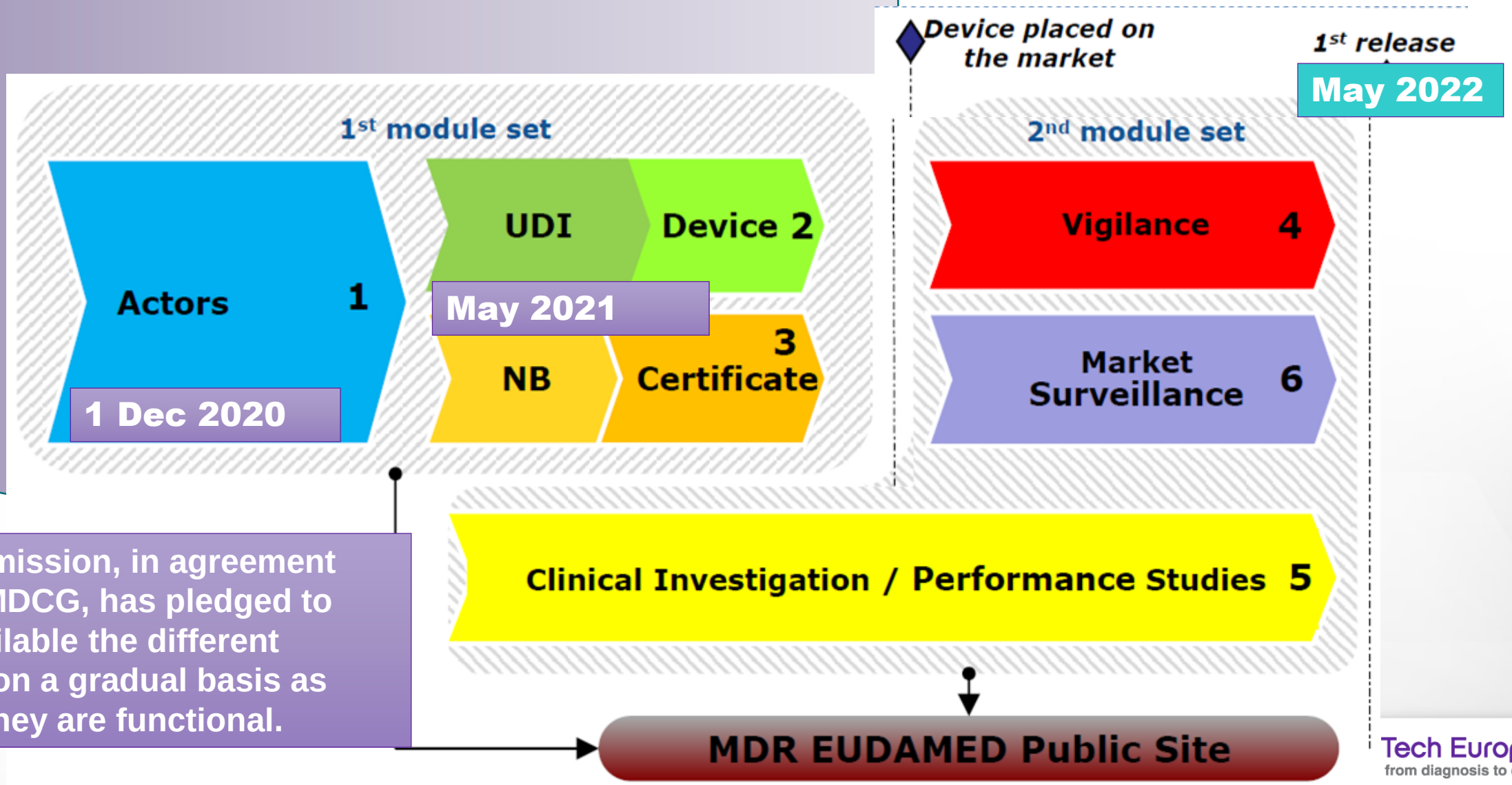
MedTech Europe
from diagnosis to cure

Part 2

New EU Database on Medical Devices (EUDAMED)

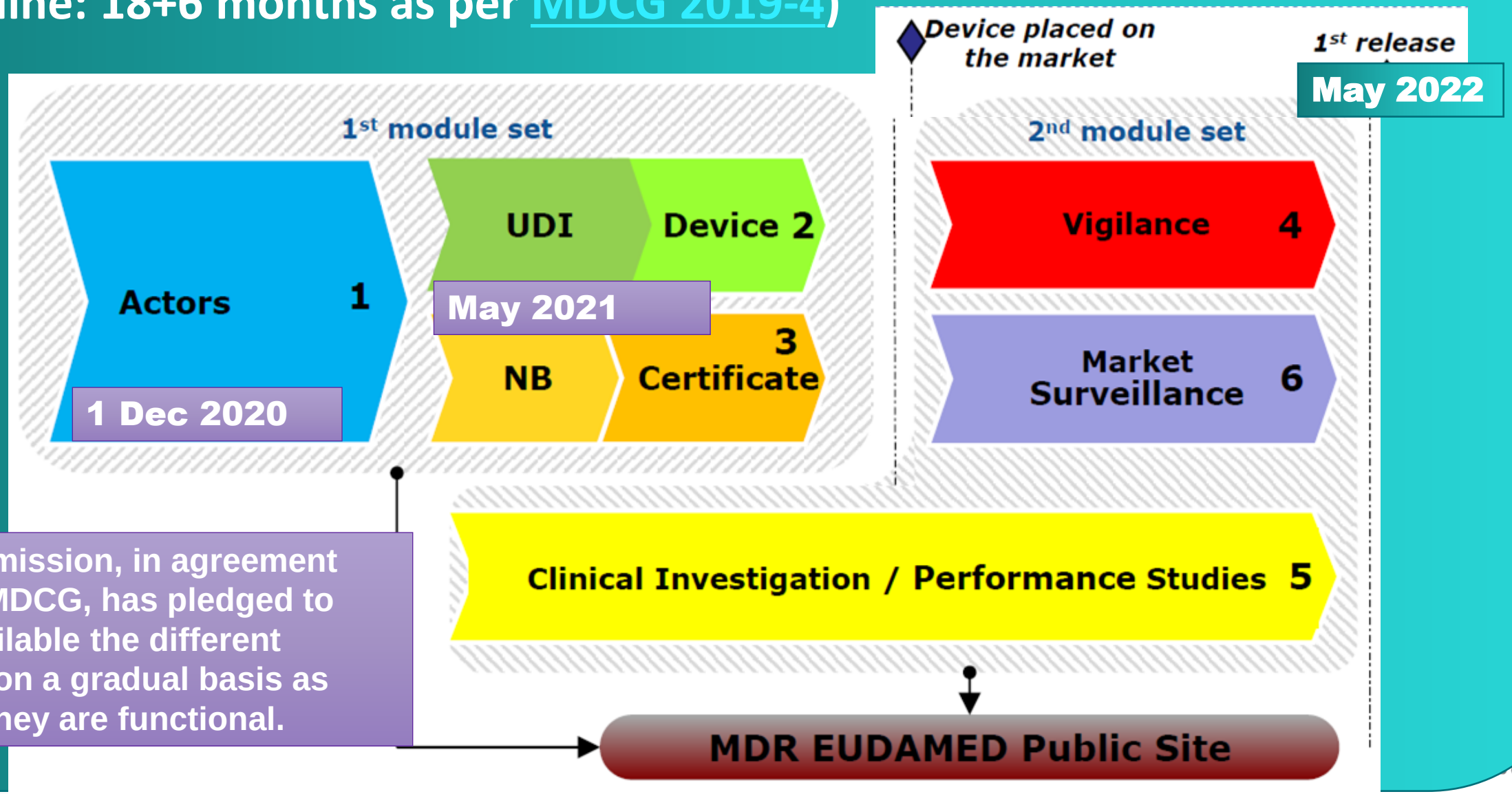
Voluntary Registration of Economic Operators

Voluntary use



The Commission, in agreement with the MDCG, has pledged to make available the different modules on a gradual basis as soon as they are functional.

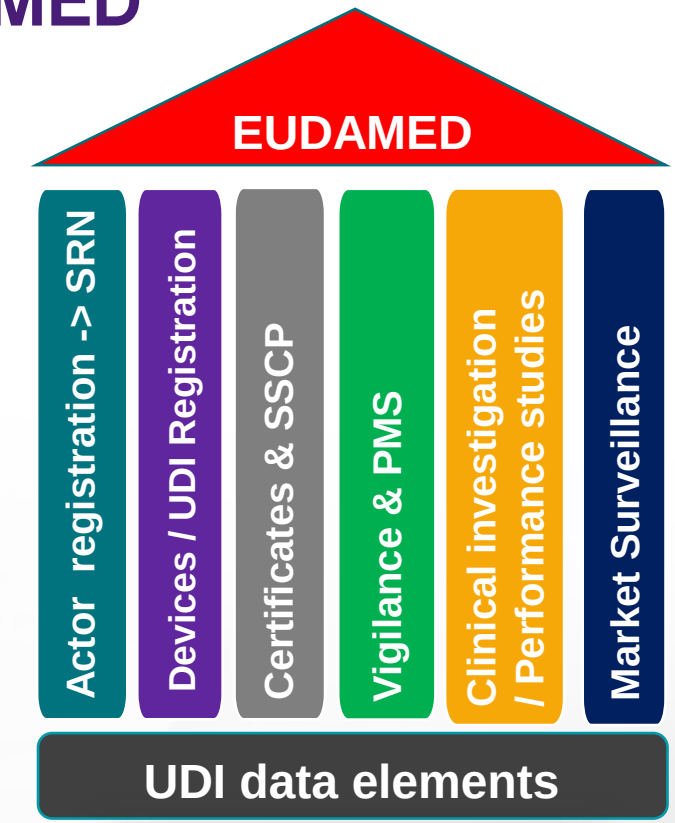
Mandatory use after 1st launch of EUDAMED completed with all modules (timeline: 18+6 months as per MDCG 2019-4)



The Commission, in agreement with the MDCG, has pledged to make available the different modules on a gradual basis as soon as they are functional.

Registration of Economic Operators in EUDAMED

- **Available from 1 December 2020 onwards in various EU Member States, on a *voluntary* basis**
  - Mandatory use of EUDAMED cannot be enforced by MDR/IVDR before database is fully functional → forecast for May 2022
  - Member States may accept to fulfill the MDR/IVDR actor registration obligation in EUDAMED in lieu of national registration (France, Belgium already confirmed)
- **Advantage of registering manufacturers, importers and authorised representatives in EUDAMED *before* May 2022**
  - Gain a Single Registration Number (SRN) = include in relevant MDR/IVDR documentation now *(no need to update regulatory documents at a later stage such as Declaration of Conformity, Technical Documentation, Certificates issued by a Notified Body, Certificate of Free Sale)*



MDCG 2020-15

MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States

August 2020

MedTech Europe
from diagnosis to cure

Commission's dedicated page for Actor registration in EUDAMED:

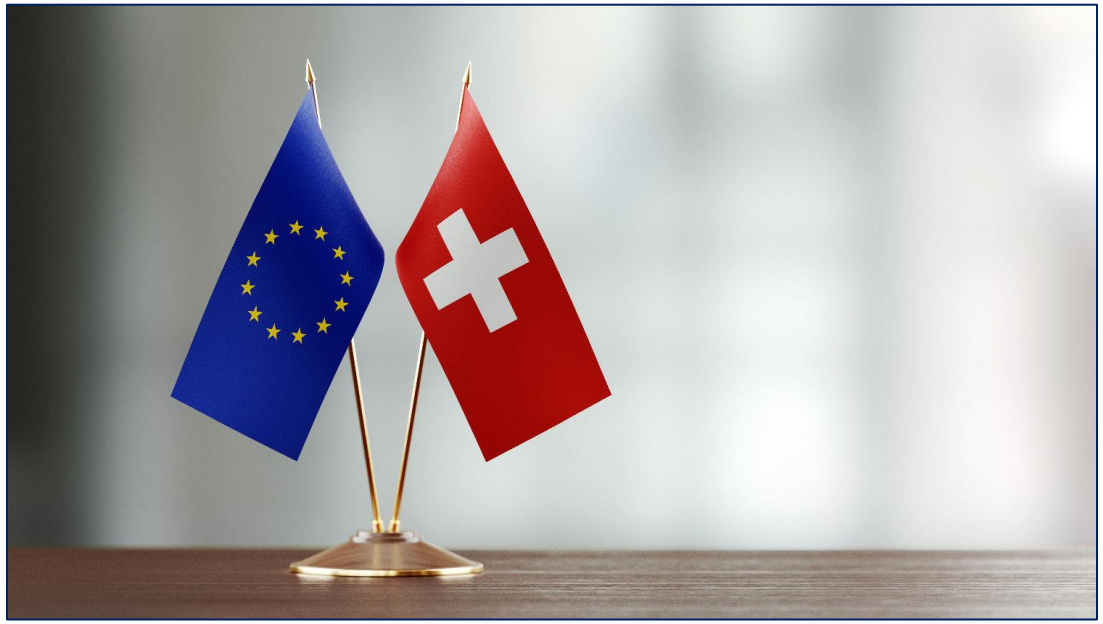
https://ec.europa.eu/health/md_eudamed/actors_registration_en

- Actor module FAQs
- Infographic: Actor roles and SRN
- Infographic: Actor registration request process
- Video: Demo actor registration module
- Guide to using EUDAMED Actor registration module

Part 3

EU-Switzerland Mutual Recognition Agreement

Possible outcomes EU-Swiss MRA



Goal — Fully update the EU-Swiss MRA

- This would require both the EU and Switzerland to agree to update the MRA – there are no technical barriers to this.
- However this is currently a political decision and there is little willingness on the side of the Commission to pursue this without pressure.

Backup — Grace Period for all

- If there is no MRA all companies both Swiss companies and those using ARs based in Switzerland need to have a grace period just like everyone else.
- This would need clarification from the EU to ensure it happens.

Reflections — Other consequences

- If there is no agreement between the EU and Switzerland it is expected that Switzerland will be setting up its own independent regulatory system for medical devices.

Part 4

EU-Turkey Customs Union

EU-Turkey Customs Agreement Framework

- Technically Turkish proposal is aligned with the MDR
- EU has provided Turkey with a proposal for agreement on GDPR (For Eudamed access)
- Turkey now needs to respond – if Turkey agrees to the Commission proposal the Customs Union agreement will be updated.

Part 5
Question Time

(…and please, stay *safe*)

regulatory@medtecheurope.org

www.medtecheurope.org

MedTech Europe
from diagnosis to cure