

MDR REVISION 2025/404

Status Quo on 2026-02-24

Armand Linge – Head of Innovation and Regulation

SWISS MEDTECH – PORTRAIT



Members

> 800 Companies



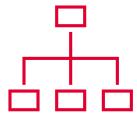
Team

13 Employees



Offices

Bern, Lugano, Lausanne



Militia system

16 Specialised Committees



Memberships

MedTech Europe, economiesuisse

AGENDA

- How did we get there?
- Current (unexpected) activities
- Potential Time Tables for the EU and for CH
- Revision Impact – direct and indirect

HOW DID WE GET THERE?

REGULATION

HOW DID WE GET THERE?

**SOME
THING
NEW**

- => **December 2025:**

MDCG Guidance on Breakthrough
Devices

[MDCG 2025-9 Guidance on Breakthrough Devices \(BtX\)
under Regulations 2017/745 & 2017/746](#)

HOW DID WE GET THERE?



- => December 2025:

2nd survey – Availability of Medical devices in the EU

[Monitoring of availability of medical devices on the EU Market - Study overview and 2nd survey results - Public Health](#)

HOW DID WE GET THERE?



- => December 2025:

Study on Regulatory Governance and Innovation in the field of medical devices in the EU

[Study on regulatory governance and innovation in the field of medical devices - Final report - EU Agenda](#)

HOW DID WE GET THERE?



- => December 2025:

MedTech Europe industry's inputs for simplification

HOW DID WE GET THERE?



- **New measures** to make EU health sector **more innovative, competitive and resilient:**
[New measures to make EU health sector more innovative, competitive and resilient](#)
- **Four** different measures were identified.
(Nota Bene: Only one is the proposal of MDR revision).

HOW DID WE GET THERE?



- 1) Proposal for a Regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors (European Biotech Act)
[Proposal for a Regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors \(European Biotech Act\) - Public Health](#)

HOW DID WE GET THERE?



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[Proposal for a Regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors \(European Biotech Act\) - Public Health](#)
- 2) Directive regarding the placing on the market of genetically modified micro-organisms and the processing of organs
[Directive regarding the placing on the market of genetically modified micro-organisms and the processing of organs - Public Health](#)

HOW DID WE GET THERE?



- 1) Proposal for a Regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors (European Biotech Act)
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- 2) Directive regarding the placing on the market of genetically modified micro-organisms and the processing of organs
[Directive regarding the placing on the market of genetically modified micro-organisms and the processing of organs - Public Health](#)
- 3) Communication on an EU cardiovascular health plan: the Safe Hearts Plan
[Communication on an EU cardiovascular health plan: the Safe Hearts Plan - Public Health](#)

HOW DID WE GET THERE?



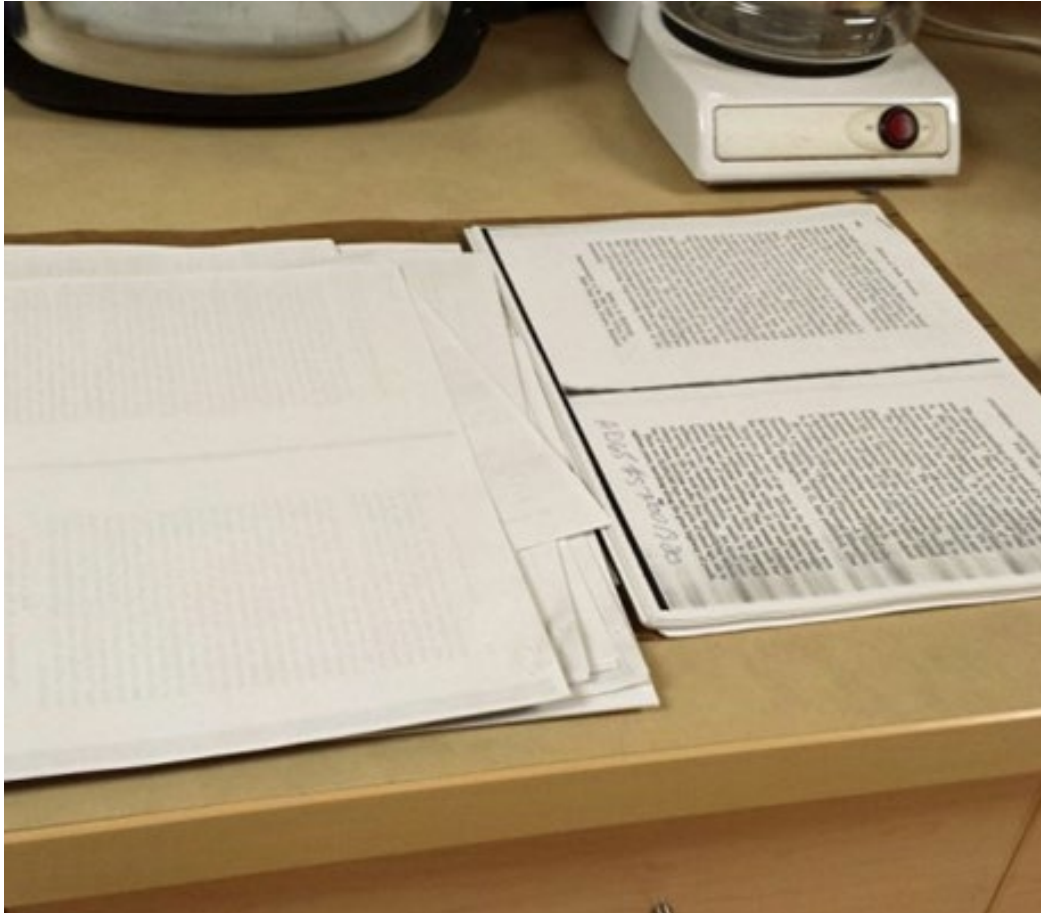
- 4a) Proposal for a regulation to simplify rules on medical (MDR)
[Proposal for a regulation to simplify rules on medical and in vitro diagnostic devices - Public Health](#)

HOW DID WE GET THERE?



- 4a) Proposal for a regulation to simplify rules on medical (MDR)
[Proposal for a regulation to simplify rules on medical and in vitro diagnostic devices - Public Health](#)
- 4b) EMA reform
[EMA Management Board: highlights of December 2025 meeting | European Medicines Agency \(EMA\)](#)

HOW DID WE GET THERE?



- Commission Staff Working Document (SWD1051)
Evaluation of medical device regulations for the
proposal to simplify and lessen regulatory
burdens

[Evaluation of medical and diagnostic device regulations for the proposal to simplify and lessen regulatory burdens - Public Health](#)

HOW DID WE GET THERE?



- Commission Staff Working Document (SWD1051) Evaluation of medical device regulations for the proposal to simplify and lessen regulatory burdens

[Evaluation of medical and diagnostic device regulations for the proposal to simplify and lessen regulatory burdens - Public Health](#)

- Commission Staff Working Document (SWD1050) on cost-savings for the proposal to reduce and simplify regulations on medical devices

[Staff working document on cost-savings for the proposal to reduce and simplify regulations on medical and diagnostic devices - Public Health](#)

HOW DID WE GET THERE?



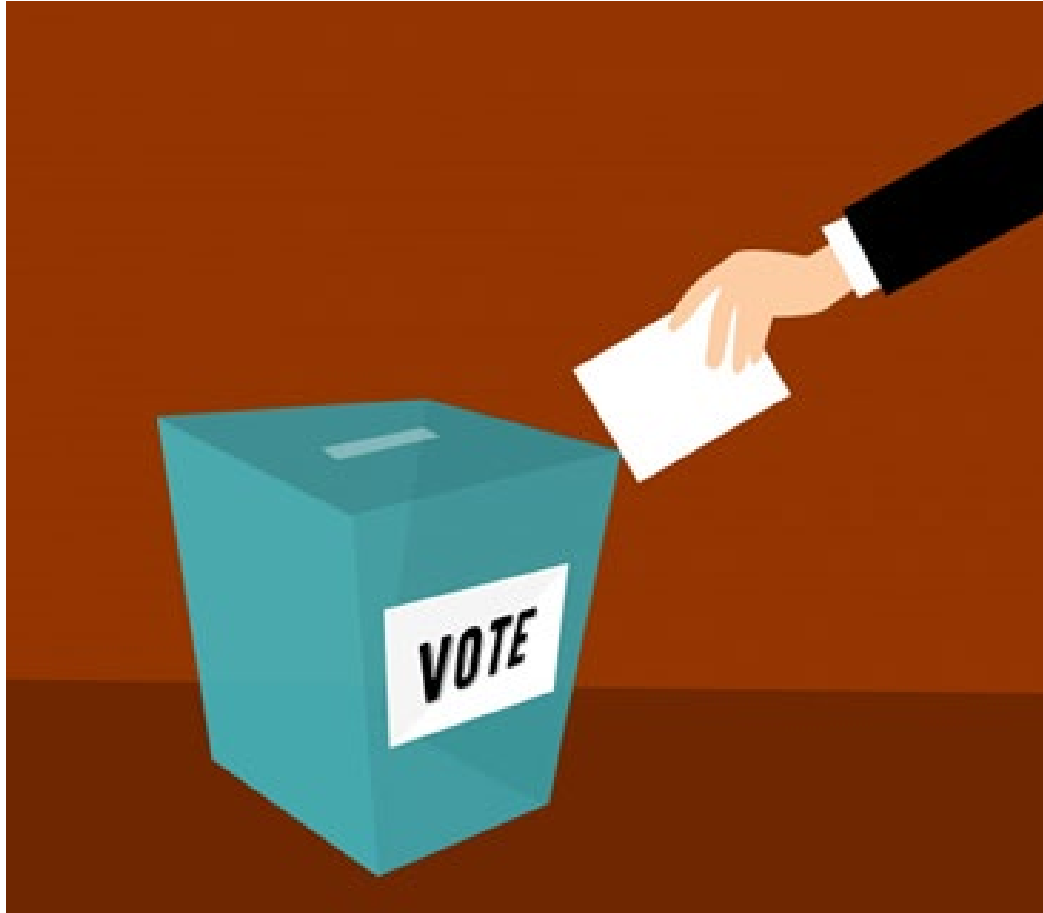
- Commission Staff Working Document (SWD1051) Evaluation of medical device regulations for the proposal to simplify and lessen regulatory burdens
[Evaluation of medical and diagnostic device regulations for the proposal to simplify and lessen regulatory burdens - Public Health](#)
- Commission Staff Working Document (SWD1050) on cost-savings for the proposal to reduce and simplify regulations on medical devices
[Staff working document on cost-savings for the proposal to reduce and simplify regulations on medical and diagnostic devices - Public Health](#)
- Nota Bene: European Commission and EIB Group announce new initiative to mobilise €10 billion investment for Europe's biotech sector
[Joint press release: European Commission and EIB Group announce new initiative](#)

HOW DID WE GET THERE?



- **«REGULATORY FITNESS AND SIMPLIFICATION»**
- 13 documents published simultaneously to
 - **Support Innovation and competitiveness**
 - **Improve predictability**
 - **Reduce administrative burden**
 - **Simplify existing rules**

HOW DID WE GET THERE?



- The EU Commission has finished its job
=> **The text is now ready to be voted.**
- **Next step:** The European Parliament is expected either to approve (or to reject) the revision 2025/0404.
- Plenary session in Strasbourg planned **on April 29th/30th.**



CURRENT (UNEXPECTED) ACTIVITIES

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- **3rd** Study supporting the monitoring of the availability of medical devices on the EU market – Deadline: 28 February 2026

[https://ec.europa.eu/eusurvey/runner/3rd EO survey](https://ec.europa.eu/eusurvey/runner/3rd_EO_survey)

CURRENT (UNEXPECTED) ACTIVITIES



- **High-level Conference** on Medical Devices in Brussels: Innovation and Patient Safety - 16 March 2026

[High-level Conference on Medical Devices: Innovation and Patient Safety - 16 March 2026 - Brussels, Belgium - Public Health](#)

CURRENT (UNEXPECTED) ACTIVITIES



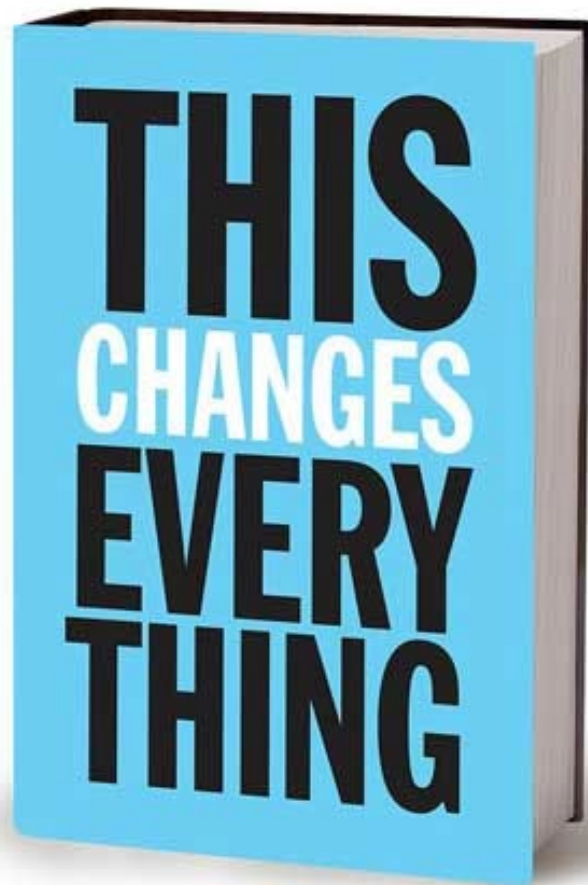
- Side effects the current EU regulations not clearly assessed
 - Considering the article 17 on **Sustainability** Activities
 - **Cybersecurity** Act.
 - **Artificial Intelligence** Regulation
 - . . .

CURRENT (UNEXPECTED) ACTIVITIES



- **On-going changes** on the current MDR 2017/745
 - **22 new harmonized standards** for medical devices already published 2026
 - **New MDCG documents** scheduled for 2026 (there were 22 new in 2025)
 - **EMDN list v3**
 - **EUDAMED go Live** from May 28th, 2026
 - **DIN SPEC 91509** Data model for the technical documentation of medical devices

CURRENT (UNEXPECTED) ACTIVITIES



- The fate of this reform is, ultimately in the hands of the EU 'co-legislator,' i.e.,
 - **the EU Parliament** - representing 700+ elected EU politicians - and
 - **the Council** - representing the 27 EU Member States' national governments.
-
- These 2 EU institutions **will** change the Commission proposal with amendments of their own.
- Many outcomes could result from this, including swift (or slow) conclusion of the legislative process, and including targeted (or substantial) changes to the content of what the EU Commission has proposed.

CURRENT (UNEXPECTED) ACTIVITIES



- Draft **Implementing Regulation** on MDR/IVDR Annex VII (requirements to be met by Notified Bodies) currently being reviewed and discussed (Trade associations with NCAs, directly with the EU Council)
- **Main topics:**
 - a) *Will NBs survive this Revision?*
 - b) *Country specific requirements*
 - c) *Varia*

CURRENT (UNEXPECTED) ACTIVITIES



- Official Position of **Swiss Medtech**:
- **Swiss Medtech** supports the simplification of the MDR and, in this sense, welcomes the EU Commission's proposed revision in principle.
- However, the association believes that **there is still room for improvement.**

POTENTIAL TIMETABLE EU / CH

REGULATION

POTENTIAL TIMETABLE EU / CH



- **Potential timetable for the EU:**
 - **Q2/2026:** the EU issues a new revision with amendments.
 - **Q3/2026:** Plenary session in Strasbourg and vote.
 - **Q1/2027:** Comes into force
 - **31.12.2027:** End of the transition period for Class III and Class IIb
 - **31.12.2028:** End of the transition period for Class IIa and Class Ir/s/m

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- **Potential timetable for the CH:**
 - **Q2/2027:** MepV update

REVISION IMPACT

REVISION IMPACT



- **1) Regulatory Affairs (1/3)**
 - **PRRC Simplified role** (article 15)
 - **Declaration of conformity** in digital form (article 19)
 - **Removal** of the certificated **validity period** (currently 5 years) (article 56)
 - **Technical Documentation content** (Annex I, II and III)
 - Technical Documentation may be drawn up **in digital form** (Article 52b)
 - Some classification rules are adapted **with lower risk classes** for certain devices like reusable surgical instruments, software and accessories to active implantable devices. (Annex VIII)

REVISION IMPACT



- **1) Regulatory Affairs (2/3)**
 - **Changes** after certification to be clarified with the NB (Annex VII)
 - **Structured dialogue** with NBs => pre- and post-submission (Annex VII)
 - **Central coordination with a decentralized system** (EUDAMED) (multiple articles and annexes)

REVISION IMPACT



- **1) Regulatory Affairs (3/3)**
 - **NBs services to be disclosed**
 - Full transparency on costs,
 - Overall costs will be reduced,
 - Transparency on timelines to be achieved,
 - “Stop the clock” concept
 - KPIs to be published for comparison (Annex VII)
 - **NBs activities under the loop**
 - NBs to be audited by EU Authorities (specific EU budget allocated)
 - **NBs future being questioned**
 - (Annex VII + draft of implementing act)

REVISION IMPACT

The image shows the cover of a manual. On the left, there is a teal-colored curved shape. The text 'ISO 13485' is written in a large, bold, black font. Below it, 'Quality Manual' is written in a smaller, bold, blue, italicized font.

ISO 13485 *Quality Manual*

- **2) Quality**
 - **ISO 13485 scope** remains the same.
 - **Updating procedures** according to the MDR revision and **train the organization**

REVISION IMPACT



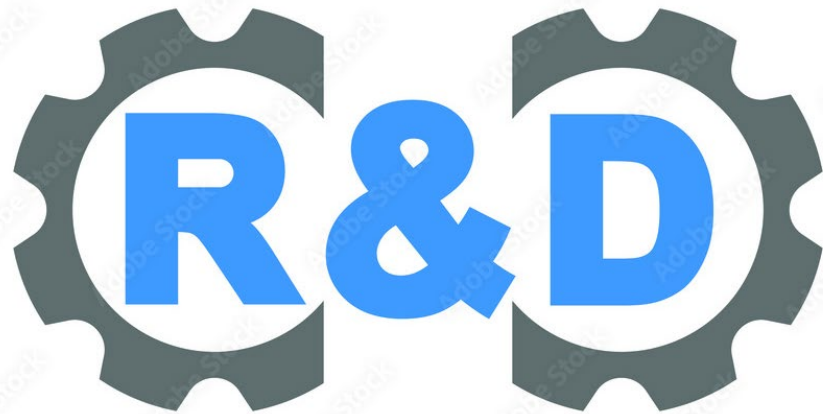
- **3) Supply Chain**
 - **Relabeling and repackaging activities** will not require a NB certificate (Article 16)
 - **Article 10a on interruption or discontinuation** of supply of certain devices to be connected with a **central IT tool** (Article 10a + EMA)

REVISION IMPACT



- **4) Sales & Marketing**
 - Reprocessing of single-use devices with a **justification for a «single use» claim** (Article 17)
 - **Economic operators need** to provide their digital contact in EUDAMED (Article 31)

REVISION IMPACT



- **5) R&D**
 - **Breakthrough devices** with new Conformity assessment procedures (new article 52a)
 - A definition of “**well-established technology device**” is introduced (article 2, point 72, Articles 18, 32, 52, 61 and 86).
 - Regulatory sandboxes to address **needs of emerging technologies** (new article 59b and 59c)

REVISION IMPACT



▪ 6) Clinical

- **A wider range of data** may qualify as clinical data for clinical evidence (Article 2, point 48, Article 61, Annex II, Annex XIV)
- SSCP scope for Class IIa, IIb and III only. **NB validation is no longer required.** (Article 32)
- **PSUR update frequency is reduced** (Article 86)
- **CECP will be limited** to Class III implantable devices (Article 54)

REVISION IMPACT



- **7) Market Surveillance**
 - **No key change identified**



CONCLUSIONS

REGULATION

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- 1) Keep on following your current plan

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- **3) Wait for the final version to be approved by the EU parliament in Strasbourg**

CONCLUSIONS



- 1) Keep on following your current plan
- 2) Liaise with your Notified Body and consider acting in the future if necessary
- 3) Wait for the final version to be approved by the EU parliament in Strasbourg
- **4) Stay in sync with your NB to maintain the regulatory compliance**
 - 3 months to perform the gap analysis
 - 3 months to update the work instructions
 - 3 months to train the organization

CONCLUSIONS



- 1) Keep on following your current plan
- 2) Liaise with your Notified Body and consider acting in the future if necessary
- 3) Wait for the final version to be approved by the EU parliament in Strasbourg
- 4) Stay in sync with your NB to maintain the regulatory compliance
- **5) Coordinate the regulatory compliance activities internally**

CONCLUSIONS



- 1) Keep on following your current plan
- 2) Liaise with your Notified Body and consider acting in the future if necessary
- 3) Wait for the final version to be approved by the EU parliament in Strasbourg
- 4) Stay in sync with your NB to maintain the regulatory compliance
- 5) Coordinate the regulatory compliance activities internally
- **6) Update your technical documentation**

CONCLUSIONS

SWISS MEDTECH

- 1) Keep on following your current plan
- 2) Liaise with your Notified Body and consider acting in the future if necessary
- 3) Wait for the final version to be approved by the EU parliament in Strasbourg
- 4) Stay in sync with your NB to maintain the regulatory compliance
- 5) Coordinate the regulatory compliance activities internally
- 6) Update your technical documentation
- **7) Stay tuned with Swiss Medtech**

THANK YOU FOR YOUR PARTICIPATION!

