IVDR – the perspective of the European Commission

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ESLHO IVDR Workshop

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EU legislation on IVDs

	Directive 98/79/EC	Regulation (EU) 2017/746
Adopted in	• 1998	• 2017
Number of articles	• 24 articles	• 113 articles
Number of annexes	• 9 annexes	• 14 annexes
Type of law	• Directive: outlines objectives to be achieved by Member States, transposed into national law	• Regulation: directly applicable to various actors, no need to be transposed into national law
Related legislation	• Directive 93/42/EEC on medical devices, Directive 90/385/EEC on active implantable medical devices	• Regulation (EU) 2017/745 on medical devices

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How the IVDR was made

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How are decisions made?

❑Legislative decisions:

❑Technical decisions:

Expert group of national competent authorities (Medical Device Coordination Group)

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Revision of the legislation

- Stage 1 - Preparation of proposals:
  - **2008-2011**: 2 public consultations on medical device framework, exploratory process on the future of medical device sector
  - **2/2012**: PIP breast implant crisis, European Parliament Resolution
  - **9/2012**: Publication of impact assessment and Commission's proposals for draft Regulations on medical devices and *in vitro* diagnostic medical devices
- Stage 2 - Negotiation and adoption by the co-legislators:
  - **4/2014**: European Parliament 1st reading vote
  - **10/2015**: Council agreement on general approach
  - **6/2016**: Council and Parliament political agreement
  - **5/2017**: publication of the Regulation in the Official Journal of the EU
- Stage 3 - Implementation

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What the new Regulation brings

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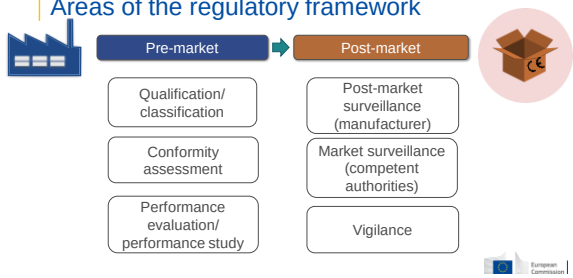
Areas of the regulatory framework



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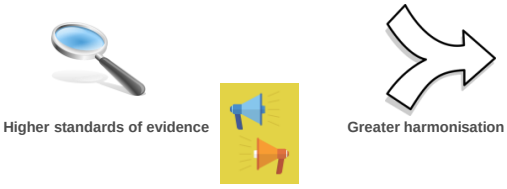
What does the new Regulation bring?



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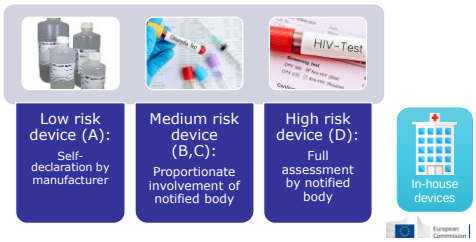
A new device classification system



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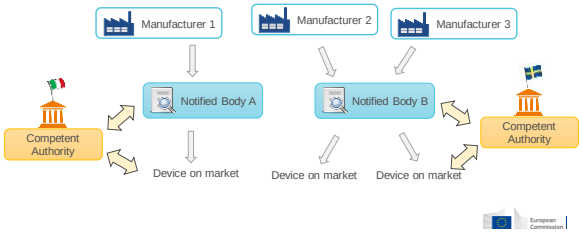
Regulatory system involving notified bodies



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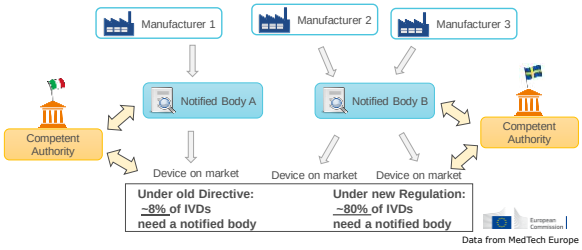

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What does the new Regulation bring?

Higher standards of evidence

Transparency and traceability

Greater harmonisation

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Implementation of the IVDR

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Progress with implementation at EU level

WHO DOES IT? Medical Device Coordination Group of national authorities and Commission + EU stakeholder associations (market operators, clinical and laboratory professionals), for legal acts also a Regulatory Committee of Member State representatives

Completed:

- Operationally necessary implementing acts
- Request on standards to standardisation body CEN/CENELEC, 1 publication in OJEU
- Unique device identifier system and helpdesk
- 6 notified bodies designated
- IVD expert panel appointed
- Various guidance on topics common to MDs and IVDs
- 5 IVD-specific guidance documents (classification, transitional provisions on class D devices, performance evaluation of SARS-CoV-2 devices, notified body codes, consultation of expert panel)
- Factsheets and other communication resources

Ongoing:

- 11 notified body applications for designation
- Implementing act on common specifications for 16 types of high-risk devices
- 5 guidance documents (performance evaluation, devices in clinical trials of medicines, batch testing, summary of safety and performance, in-house devices)
- Establishment of EU reference laboratories for high risk devices
- Monitoring and contingency planning

More info on Commission website: https://ec.europa.eu/health/md_sector/new_regulations_en
See rolling plan, joint implementation plan on IVDR, ongoing guidance development docs bottom of page

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What are implementing acts and guidance?

- Implementing acts:
  - adopted by European Commission based on a favourable vote of Member States
  - legally binding
  - Published in the Official Journal of the European Union in all EU languages
- Guidance documents:
  - endorsed by Medical Device Coordination Group
  - not legally binding
  - Published on the European Commission's medical devices website in English

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Signs of insufficient readiness in 2021

Capacity of notified bodies

- Under Directive, 18 NBs cover ~8% of market
- Under IVDR, ~80% of market needs to be covered and only 5 NBs designated so far

Readiness of industry

- Conformity assessment takes about a year
- Several thousand NB certificates will need to be issued
- Sept 2021: 512 applications submitted to NBs and 31 certificates issued!

Readiness of healthcare institutions

- Insufficient awareness of new requirements especially on in-house devices
- Unfamiliar – hard to implement

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Calls for action to the Commission

- European Parliament cross-party letter (EPP, S&D, Renew, ECR, GUE/NGL, Greens/EFA) of 11 May 2021 to Commission President
- EPSCO-Health Council Conclusions 15 June 2021
- Stakeholders (industry, notified bodies, health professionals, laboratories, blood establishments)

EPSCO – Employment, Social Policy, Health and Consumer Council of the EU (council of ministers)

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Reflection on courses of action

- With the Medical Device Coordination Group of Member State authorities
- Discussions with stakeholders (industry, notified bodies, health professionals, laboratories, patients, consumers)

Guiding principles:

- Ensure safety and performance of devices by implementing the new Regulation as soon as possible
- Ensure continuous supply of devices to patients
- Take effective action – avoid simply postponing the problem
- Legislative action on its own is not enough – continued engagement needed from actors

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Commission proposal COM(2021)627 of 14 October 2021 on amending transitional provisions

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Commission proposal - content

- Date of application (26 May 2022) **maintained**
- Extension of transitional provisions (scope and timelines):
  - Devices with a notified body (NB) certificate under Directive 98/79/EC and requiring NB assessment under Regulation (EU) 2017/746 (Directive 98/79/EC Annex II List A and B; self-tests) - extend transition period by 1 year until 26 May 2025
  - Devices with a Declaration of Conformity (DoC) under Directive 98/79/EC and requiring NB involvement under Regulation (EU) 2017/746 – risk-based approach
    - class D – provide transition period until 26 May 2025
    - class C – provide transition period until 26 May 2026
    - class B and class A sterile – provide transition period until 26 May 2027
  - In-house devices, i.e. those subject to Article 5(5) of Regulation (EU) 2017/746:
    - maintain the exemption as under Directive 98/79/EC from 26 May 2022
    - provide transition period until 26 May 2024 for requirements in Art. 5(5), points (b), (c), (e) – (i)
    - provide transition period until 26 May 2028 for requirement in Art. 5(5), point (d)

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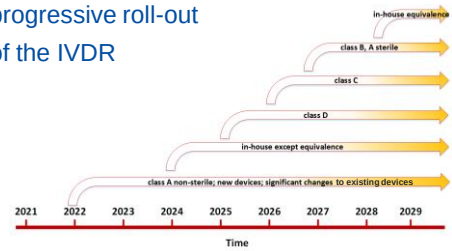
Proposal for progressive roll-out of the IVDR



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Commission proposal on Art 5(5)

With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:
(a) the devices are not transferred to another legal entity; — **May 2022**

(b) quality management system;
(c) standard EN ISO 15189 or where applicable national provisions; — **May 2024**

(d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market; — **May 2028**

(e) information to competent authority;
(f) public declaration;
(g) documentation on class D devices;
(h) measures to follow the documentation referred to in point (g); and
(i) review of experience and corrective actions. — **May 2024**

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions. — **May 2022**

This paragraph shall not apply to devices that are manufactured on an industrial scale.

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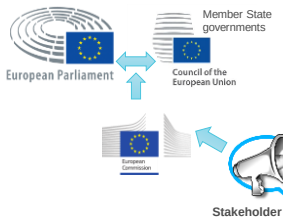
How are decisions made?

❑Legislative decisions:



❑Technical decisions:

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Next steps

- Adoption as a Regulation by the European Parliament and the Council
- Medical Device Coordination Group and Commission continue work according to the Joint Implementation Plan
- Continued market monitoring
- Complementary actions to increase notified body capacity

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- Continued market monitoring
- Complementary actions to increase notified body capacity
- **Engagement from all actors needed to make sure that safe, performant devices and innovative devices are available to patients**

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Thank you

More information:
Commission medical devices homepage: https://ec.europa.eu/health/md_sector/overview_en
Guidance page: https://ec.europa.eu/health/md_newregulations/guidance_en
Factsheets: https://ec.europa.eu/health/md_newregulations/getting_ready_en
Expert group register for composition of groups and minutes of meetings: https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3565

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What does the new Regulation bring?

Higher standards of evidence

- Stricter requirements for designation of notified bodies
- More adequate, risk-based device classification system
- Greater involvement of notified bodies in conformity assessment
- Stronger and clearer requirements for performance evaluation and post-market surveillance of devices
- New scientific structures for high-risk devices: expert panels and EU reference laboratories

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What does the new Regulation bring?

Transparency and traceability

- Centralised information in the new Eudamed database
  - Comprehensive database of devices and economic operators
  - Substantial parts available to the public
- Unique Device Identifier system
- For devices of higher risk classes, summary of safety and performance for the user and, if relevant, to the patient

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What does the new Regulation bring?

Greater harmonisation

- Regulation (directly applicable) vs Directive (needs to be transposed)
- Clearer obligations for various economic operators
- EU-level conditions for devices manufactured and used in the same health institution
- Greater cooperation between Member States (Medical Device Coordination Group)
- Greater cooperation between notified bodies (coordination group)

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In-house devices exemption

- Manufactured and used in the same health institution for a medical purpose
- Excluded from most of the IVDR
- Some of the conditions (not exhaustive, see Art 5(5)):
  - ✓ No transfer to another legal entity
  - ✓ Manufacturing under an appropriate quality management system
  - ✓ Health institution justifies in its documentation that the patient's needs cannot be met by a marketed device
  - ✓ It provides a publicly available declaration
  - ✓ For class D (highest risk) devices, the health institution draws up documentation about manufacturing
  - ✓ Member States have the right to inspect the health institution

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