The implementation of the Medical Device Regulations

Review from the European Commission: challenges and proposals

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ESC
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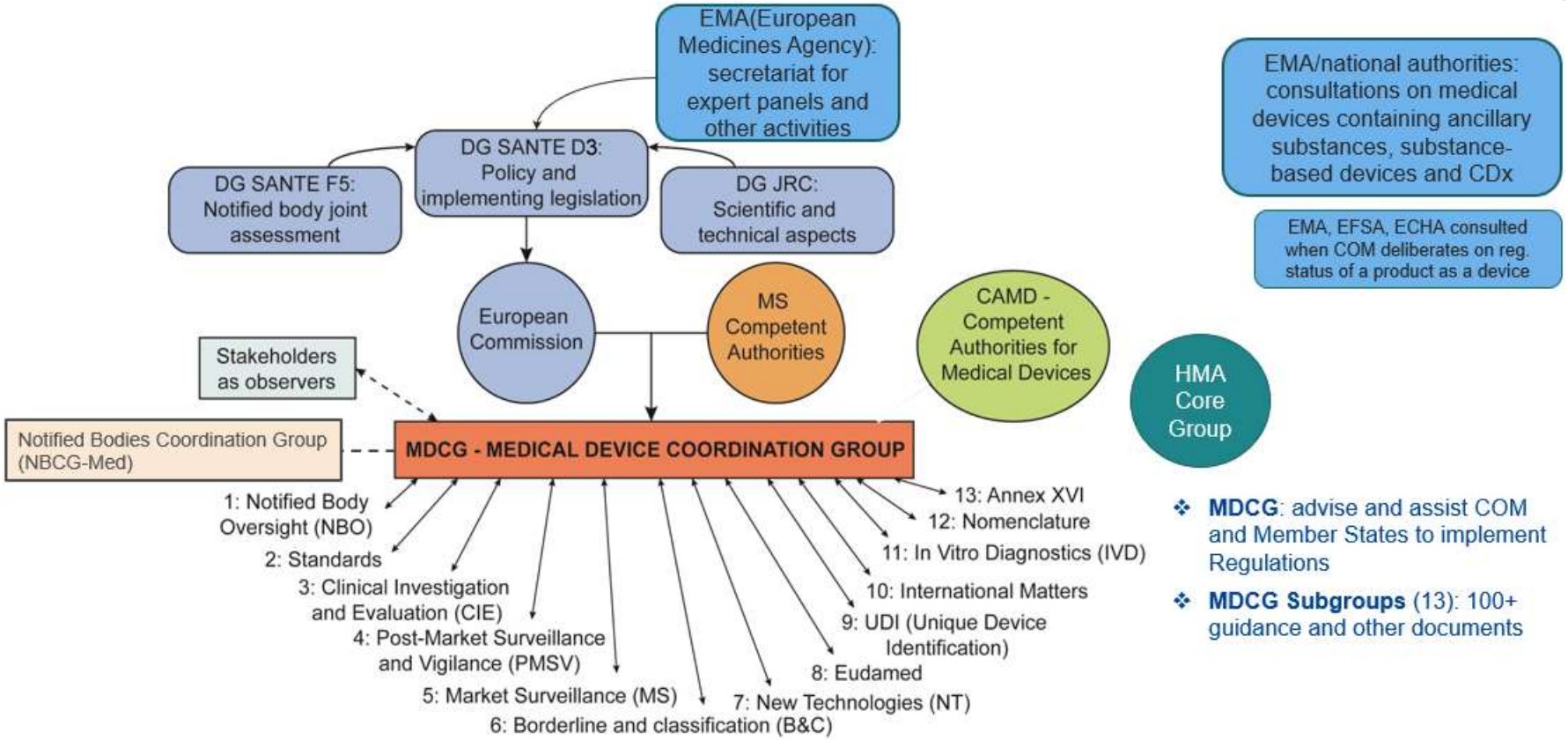
EU legislation on medical devices: objectives and main features

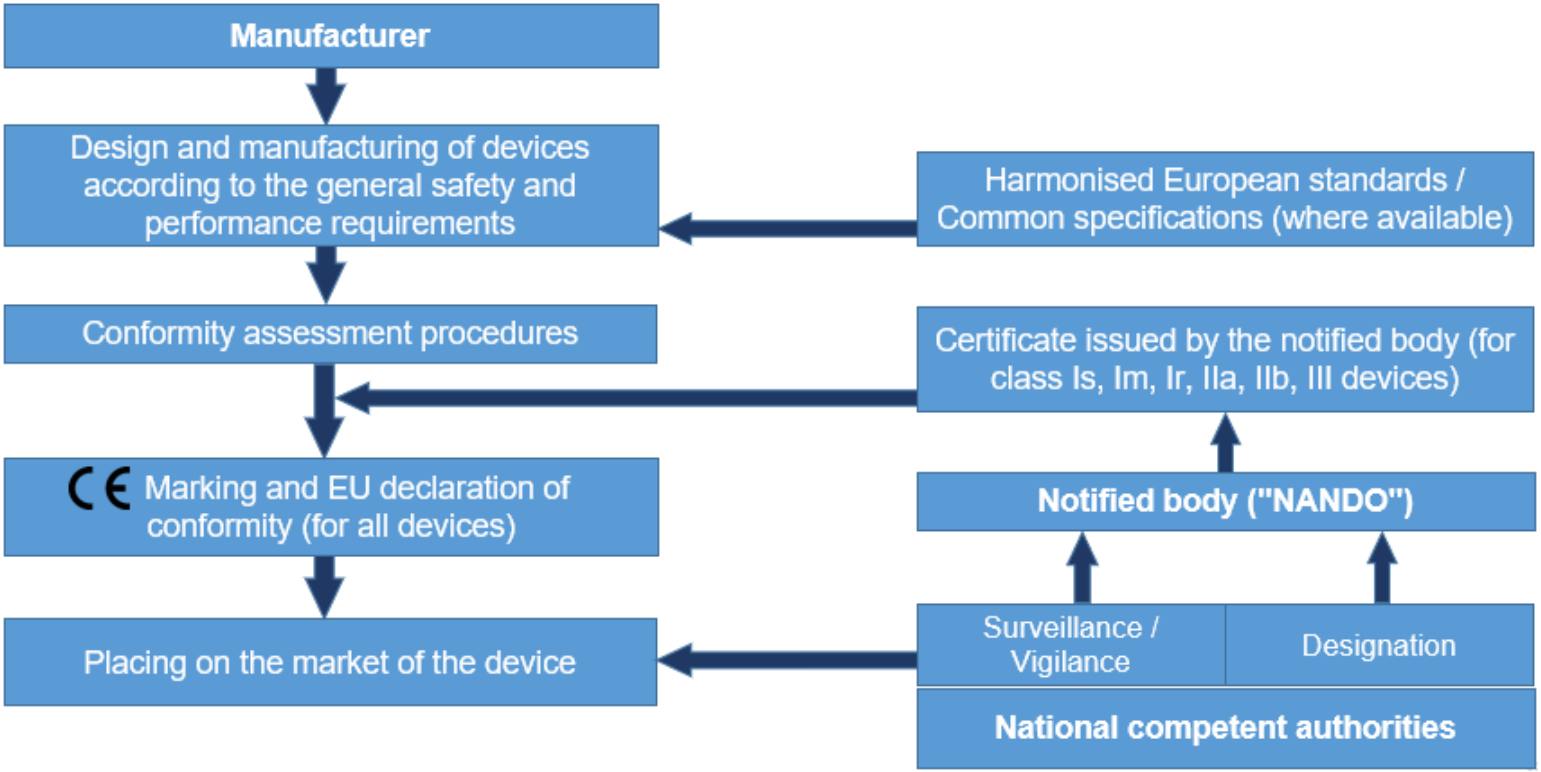
- Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), replacing the previous Directives 90/385/EEC, 93/42/EEC and 98/79/EC, aim to:
  - establish a **harmonised**, **modernised** and more **robust, transparent and sustainable** EU regulatory framework on medical devices, while ensuring **free and fair trade** of devices throughout the EU internal market
  - keep up with **advances in science and technology**, adapting EU legislation to the significant scientific and technological progress in the sector, while continuously accompanying and **supporting innovation**
  - ensure a better and consistently **high level of health and safety protection of public health and patient safety** for citizens using medical devices in the EU
- They have been developed according the "New Approach" and "New Legislative Framework" policies, with a number of **specificities** in particular on economic operators, common specifications, notified bodies, clinical evaluations and investigations, post-market surveillance, expert laboratories and panels, information, traceability and registration, etc.

EU-level governance for medical devices

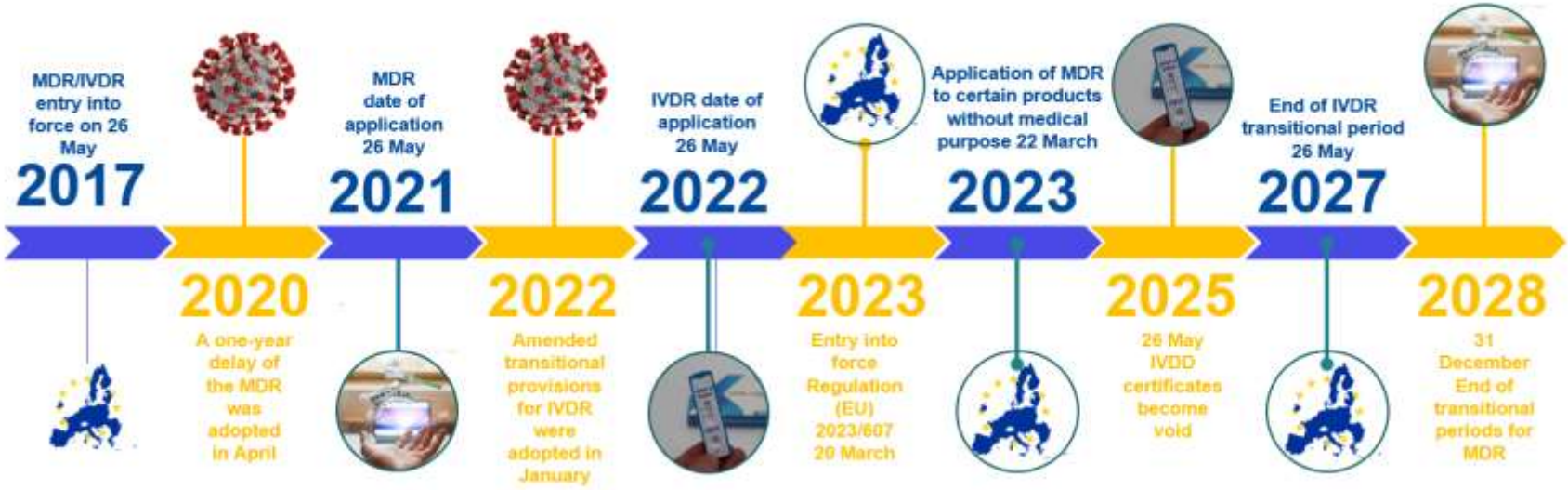


- **MDCG**: advise and assist COM and Member States to implement Regulations
- **MDCG Subgroups** (13): 100+ guidance and other documents

Medical Devices (MDR) – Basic Operational Scheme (NLF)



MDR and IVDR timelines



Implementation of the EU Regulations on medical devices and main challenges

- Coherent and pragmatic application of transitional provisions for different types of devices to prevent potential shortages of existing and new/innovative devices
- Availability and capacity of notified bodies (currently 45 for the MDR and 12 for the IVDR in the SMCS-NANDO system)
- Availability of harmonised standards (currently 25 for the MDR and 13 for the IVDR in the OJEU)
- Adoption and enforcement of implementing and delegated acts for different aspects of the Regulations (reprocessing, Annex XVI products, certain IVDs, reference laboratories…)
- Establishment of the EU reference laboratories (EURLs) for the IVDR
- Implementation on the new rules on clinical/performance evaluation and investigation
- Development and operation of the European database on medical devices ("Eudamed") and its modules
- Adequate preparedness of all the concerned parties, including manufacturers and other economic operators (especially SMEs), competent authorities in charge of market surveillance and vigilance, conformity assessment bodies, etc.

Implementation of the EU Regulations on medical devices: national provisions

- Certain aspects of the EU Regulations on medical devices and *in vitro* diagnostic medical devices are intended to be the object of specific national provisions in the EU Member States, for instance:
  - Single-use devices and their reprocessing (Article 17 MDR): see the list of "National rules on reprocessing of single-use devices" https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices/national-rules-reprocessing-single-use-devices_en
  - Registration of distributors of devices (Article 30 MDR, Article 27 IVDR)
  - Assessment, designation and notification of conformity assessment bodies, and monitoring of notified bodies (Article 35 MDR, Article 31 IVDR): see "Notifying authorities" https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notifying-authorities and "Designating Authorities" https://ec.europa.eu/tools/eudamed/#/screen/designating-authorities
  - Market surveillance (Article 93 MDR, Article 88 IVDR)
  - Fees (Article 111 MDR, Article 104 IVDR)
  - Penalties (Article 113 MDR, Article 106 IVDR)

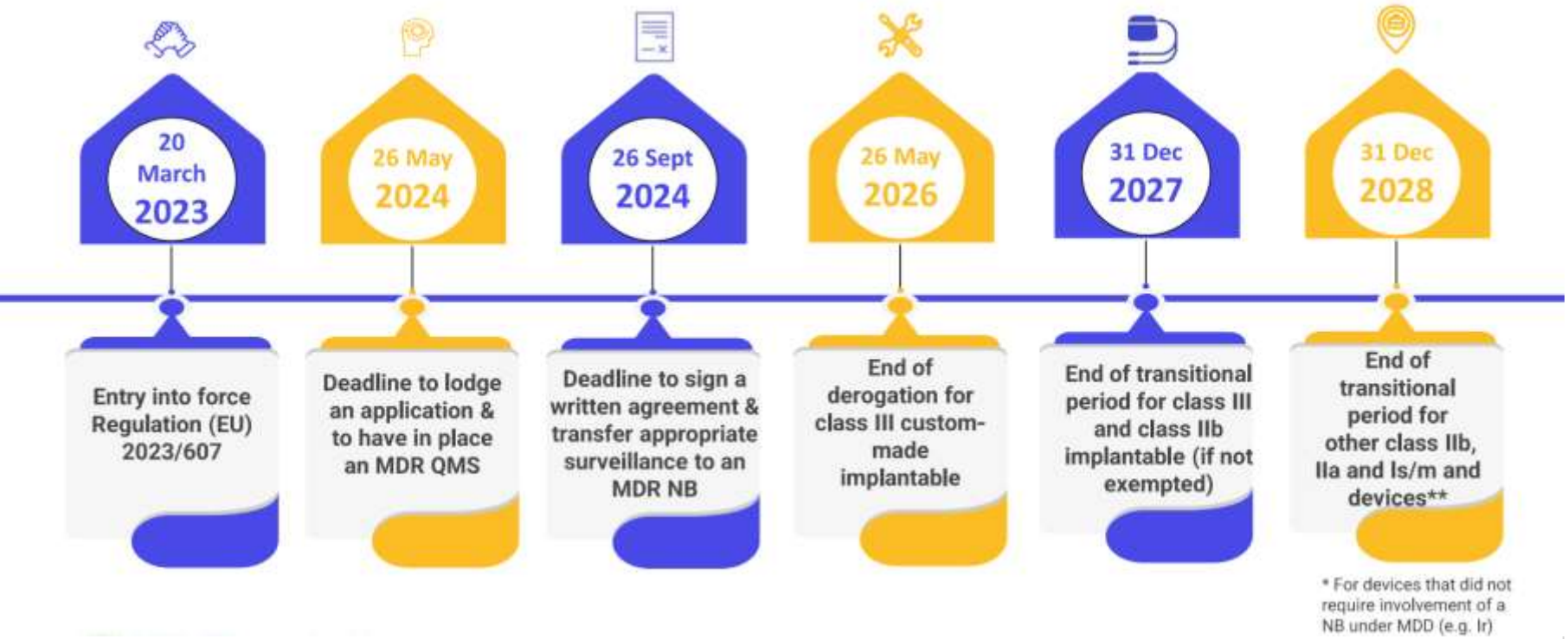
Implementation of the EU Regulations on medical devices: key references

- Sectorial challenges - Public health systems, access to healthcare, sustaining innovation: https://health.ec.europa.eu/medical-devices-sector/overview_en#sectorial-challenges
- Implementing measures for the Regulations: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#implementing-measures-for-regulations
- Delegated acts adopted under the regulations: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#delegated-acts-adopted-under-the-regulations
- Guidance documents: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
- Ongoing/planned guidance development and deliverables of the MDCG Subgroups: https://health.ec.europa.eu/document/download/f588a5c8-57af-48aa-808f-1d9c02f4925a_en?filename=mdcg_ongoing-guidance_0.pdf
- Extension of the transition periods provided for in the Regulations: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#extension-of-the-transition-periods-provided-for-in-the-regulations

Amendments to the Regulations: staggered extension of the transition periods

- Regulation (EU) 2022/112 amending the IVDR as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices: adopted in January 2022
  - allowing for the progressive rollout of the IVDR regarding *in vitro* diagnostics covered by a certificate or a declaration of conformity issued in accordance with the previous Directive 98/79/EC
- Regulation (EU) 2023/607 amending the MDR and IVDR as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices: adopted in March 2023
  - introducing a staggered extension of the transition period provided for in the MDR, subject to certain conditions
  - deleting in both MDR and IVDR the “sell-off” deadline after which devices placed on the market before or during the transition periods that are still in the supply chain would have had to be withdrawn
- Proposal COM(2024)43 for a Regulation amending the MDR and IVDR as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain *in vitro* diagnostic medical devices: submitted in January 2024

MDR transitional period per Regulation (EU) 2023/607: timeline



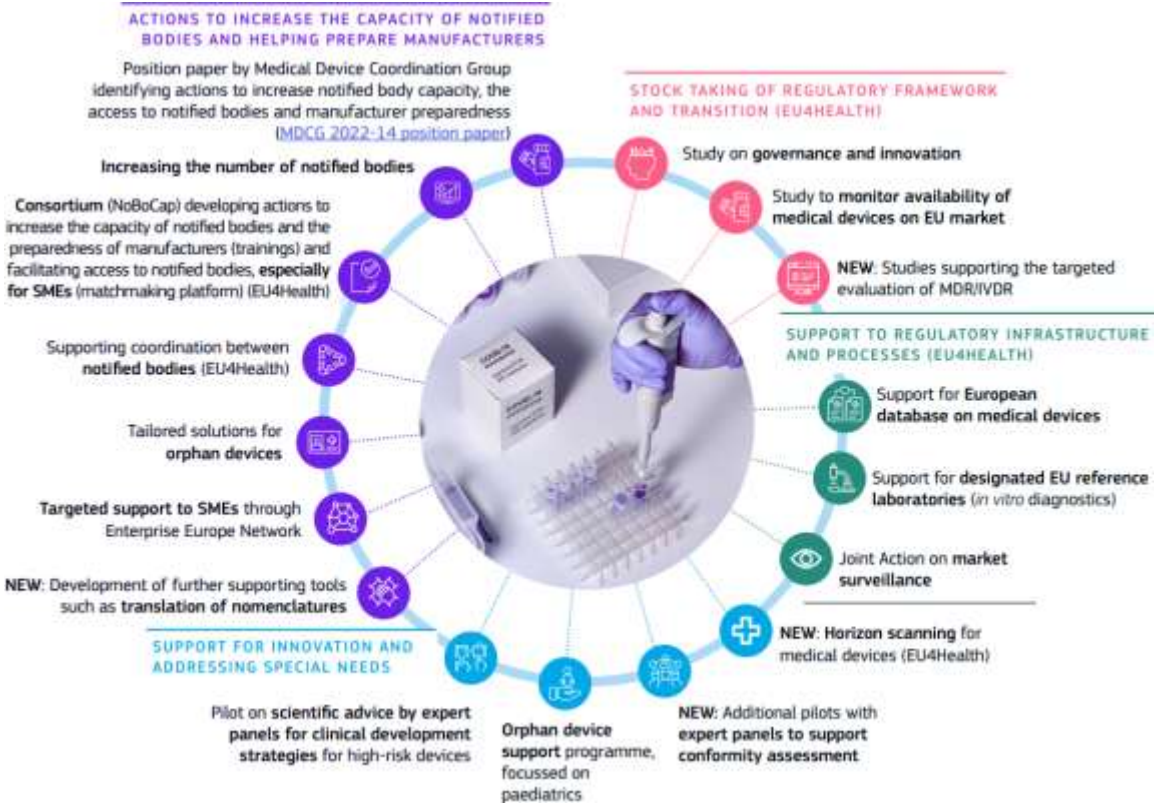
IVDR transitional period per Proposal COM(2024)43: timeline

- The proposed new transition periods will depend on the type of device, specifically its risk class under the IVDR

- Further extension of the transition period for *in vitro* diagnostic medical devices:
  - to 31 December 2027 for high risk devices
  - to 31 December 2028 and 31 December 2029 for medium and lower risk devices respectively

- Subject to specific conditions

Ongoing non-legislative actions to support the implementation of the MDR and IDVR and the transition



Information and communication

- European Commission's Directorate-General Health and Food Safety (DG SANTE) – Public Health – Medical Devices - Sector: https://health.ec.europa.eu/medical-devices-sector_en
  - Unit D3 Medical Devices: SANTE-MED-DEV@ec.europa.eu

- Communication campaign on the MDR and IVDR:
  - "MEDICAL DEVICES NEWS" newsletter: latest issue, December 2023 https://ec.europa.eu/newsroom/sante/newsletter-archives/50009
  - Stakeholder database: https://hadeamdrivdr.actionpublicsector.com/contact/

- Social networks:
  - EU Health and Food Safety in LinkedIn: https://www.linkedin.com/showcase/eu-health-and-food-safety/
  - EU Health - #HealthUnion in Twitter/X: https://twitter.com/EU_Health