NoBoCap COMMUNITY

QUALIFY TO CERTIFY


# SUMMIT UNLOCKING MDR/IVDR REGULATIONS FOR INNOVATORS IN EUROPE

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**

Brussels

Co-funded by the European Union

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# WELCOME

Co-funded by the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

## Moderator Amanda Maxwell

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# Yves Verboven
# EU4HealthSolutions

Co-funded by the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# IMPACT OF MDR/IVDR ON INNOVATION AND THE NOBOCAP COMMUNITY "A VOICE FOR INNOVATORS/SMEs in EUROPE TO KEEP THE PULSE "

09:00–10:00

**WEDNESDAY**
**SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

Co-funded by the European Union

# EU4Health Study supporting the monitoring the availability of medical devices on the EU market

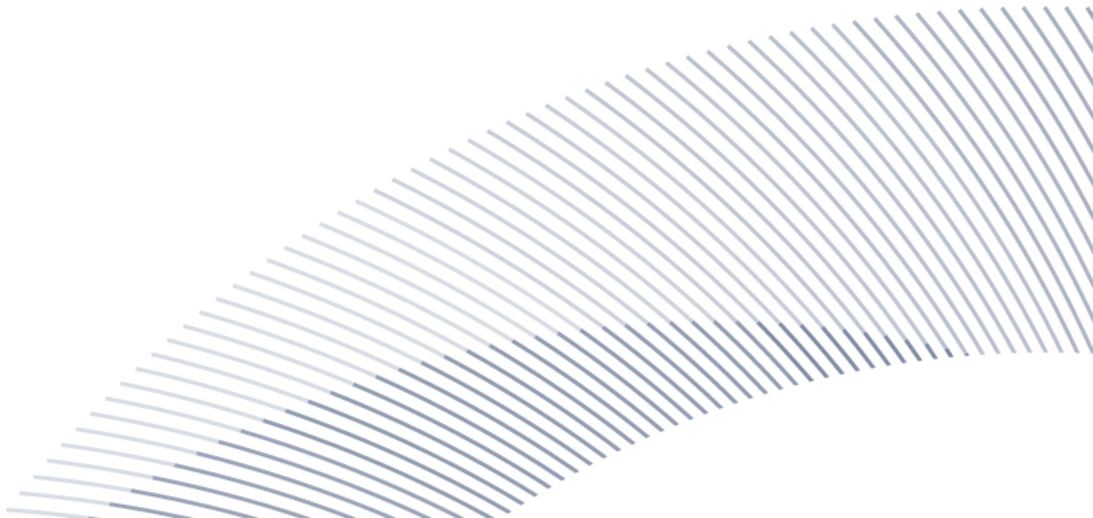
NOBOCAP COMMUNITY SUMMIT 2024
25 September 2024, 9.00-10.00

Friederike Windisch, Nina Zimmermann

# Overview

1. About the study
2. Dashboard
3. Surveys
    - Overview of ongoing and planned survey activites
    - Survey with notified bodies
    - Survey with manufacturers and authorised representatives

# 1. About the study



# About the ‘Study supporting the monitoring of availability of medical devices on the EU market’

**Commissioned by:**
The European Commission’s Directorate-General for Health and Food Safety (DG SANTE)
via the European Health and Digital Executive Agency (HaDEA) - **HADEA/2021/P3/03**

**Aim:** To support monitoring and analyzing the availability of medical devices and in vitro diagnostic medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic medical devices Regulations **from the perspectives of key stakeholders**

**Geographic scope:** 30 countries (27 EU Member States plus Iceland, Liechtenstein and Norway)

**Duration:**
2 December 2022 – 1 December 2025 (36 months)

**Study team:**

- **Project lead:** Gesundheit Österreich GmbH (GÖG) / Austrian National Public Health Institute → project lead
- **Project partners:** Areté, Civic Consulting
- **Supported by an Expert Advisory Group:** Four MD experts providing methodological and thematic support

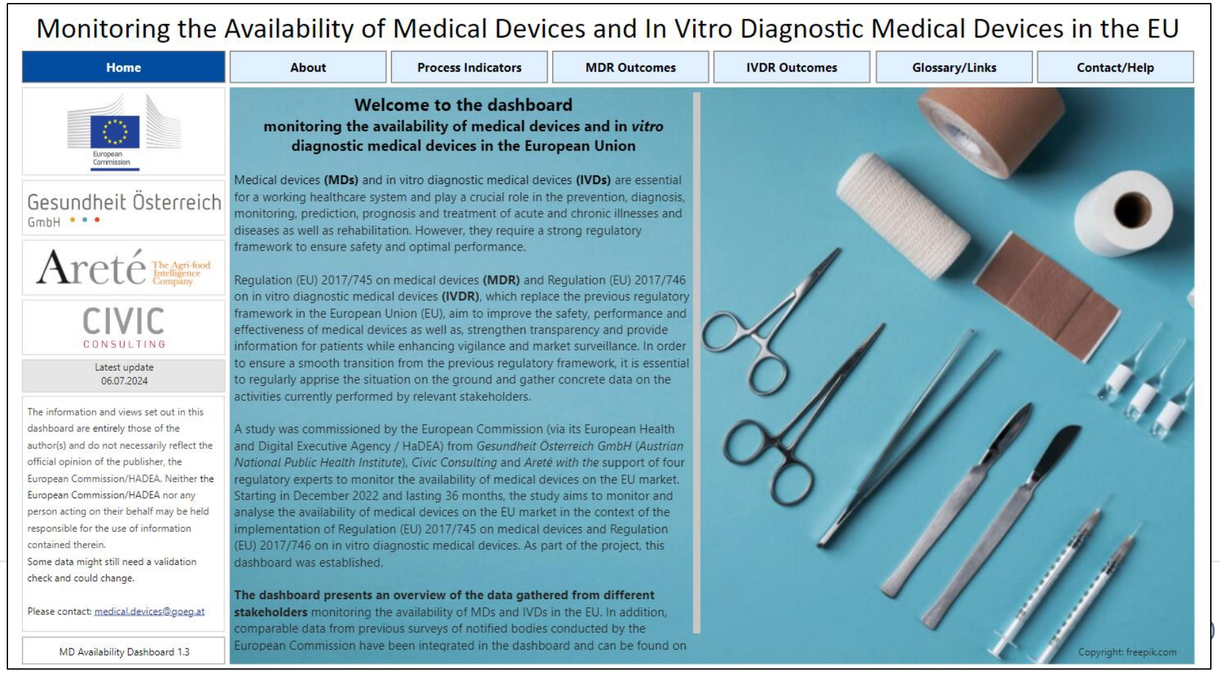
**Contact:** Ms Friederike Windisch (project manager), Ms Nina Zimmermann (deputy project manager) → medical.devices@goeg.at

# 2. Dashboard

# Dashboard published on 9 January 2024

- Study results are presented in aggregated form in a **publicly available** and **regularly updated** dashboard
- Content *(data status 18/09/2024, version 1.3):*
  - Results of nine notified body surveys:
    March 2023, April 2023, May 2023, June 2023, August 2023, October 2023, December 2023, February 2024, April 2024
  - Data available from previous surveys starting in 2021 (conducted by the European Commission)
  - Dashboard version 2.0 will include results of the 1st MF/AR survey

## LINK to the study and dashboard

# 3. Surveys

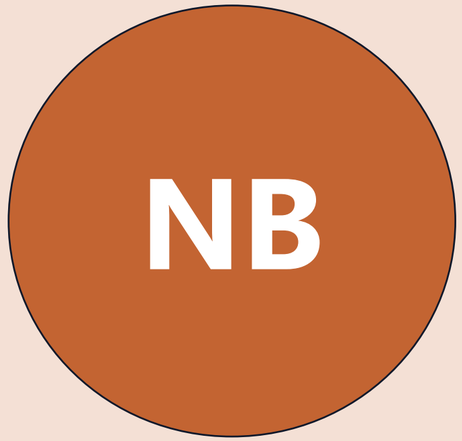
Source: © Pixabay.com

Gesundheit Österreich GmbH

# Overview of ongoing and planned survey activities

| Key stakeholder groups | Overview and status of the survey activities |
|---|---|
| **1. Notified bodies** | • NB surveys #1-9: completed<br>• NB survey #10: data validation phase<br>• NB survey #11: currently ongoing<br>• NB survey #12: preparation phase<br>• NB survey #13-17: planned for 2025 |
| **2. Manufacturers and authorized representatives** | • MF/AR survey #1: results will be published in 09/2024<br>• MF/AR survey #2: preparation phase |
| **3. Health service providers, medical societies, medical doctors** | • currently ongoing |
| **4. Patient representatives** | • preparation phase |
| **5. Competent authorities** | • preparation phase |

# Survey with notified bodies (NB)



# NB survey overview

NB surveys already conducted by the study team

| NB Survey | Survey period (survey launch – survey closure) | Requested dataset* SD = small dataset MD = medium dataset LD = large dataset | Requested data | Response rate |
|---|---|---|---|---|
| **1st** NB survey | 03/04/2023 - 05/05/2023 | SD1 + MD1 | from designation up to 31/03/2023 | 39 out of 39 NBs** **100%** |
| **2nd** NB survey | 12/05/2023 - 05/06/2023 | SD2 | from designation up to 30/04/2023 | 27 out of 39 NBs** **~ 70%** |
| **3rd** NB survey | 05/06/2023 - 19/06/2023 | SD3 | from designation up to 31/05/2023 | 22 out of 39 NBs** **~ 56%** |
| **4th** NB survey | 03/07/2023 - 28/07/2023 | SD4 + MD2 | from designation up to 30/06/2023 | 39 out of 39 NBs** **100%** |
| **5th** NB survey | 01/09/2023 - 06/10/2023 | SD5 | from designation up to 31/08/2023 | 40 out of 40 NBs** **100%** |
| **6th** NB survey | 03/11/2023 - 22/12/2023 | SD6 + MD3 + LD1 | from designation up to 31/10/2023 | 41 out of 41 NBs** **100%** |
| **7th** NB survey | 08/01/2024 - 05/02/2024 | SD7 | from designation up to 31/12/2023 | 45 out of 45 NBs** **100%** |
| **8th** NB survey | 04/03/2024 - 20/03/2024 | SD8 + ~~MD4~~ | from designation up to 29/02/2024 | 45 out of 45 NBs** **100%** |
| **9th** NB survey | 02/05/2024 – 21/06/2024 | SD9 | from designation up to 30/04/2024 | 48 out of 48 NBs** **100%** |

presentation of selected results

Survey results included in the published dashboard

* Datasets:
- The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months.** Note: From April to July 2023, it was asked monthly.
- The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
- The **large dataset** contains additional data asked to notified bodies **once a year**.

** designated under MDR and/or IVDR

# MDR applications filed and certificates issued (sum of Annexes)

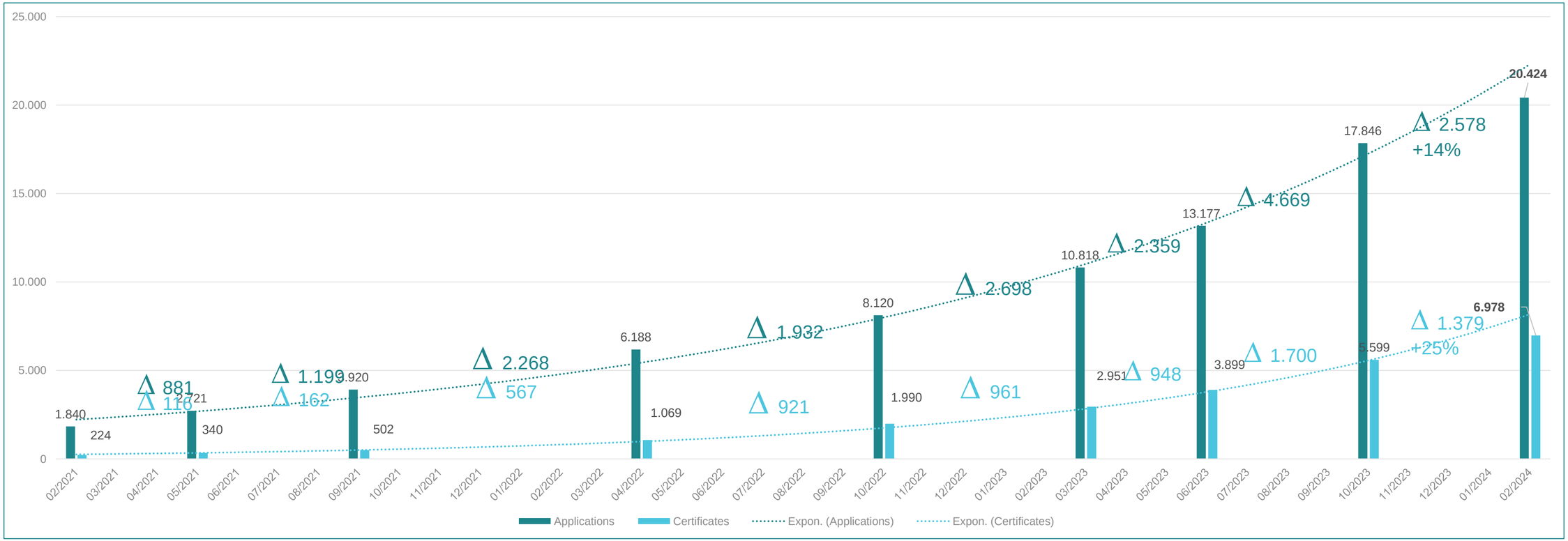
MD

Ⓜ

**February 2024**

**MDR Applications:**
Total number of applications filed by Annex Ⓜ: 20.424*

**MDR Certificates:**
Total number of certificates by Annex Ⓜ: 6.978

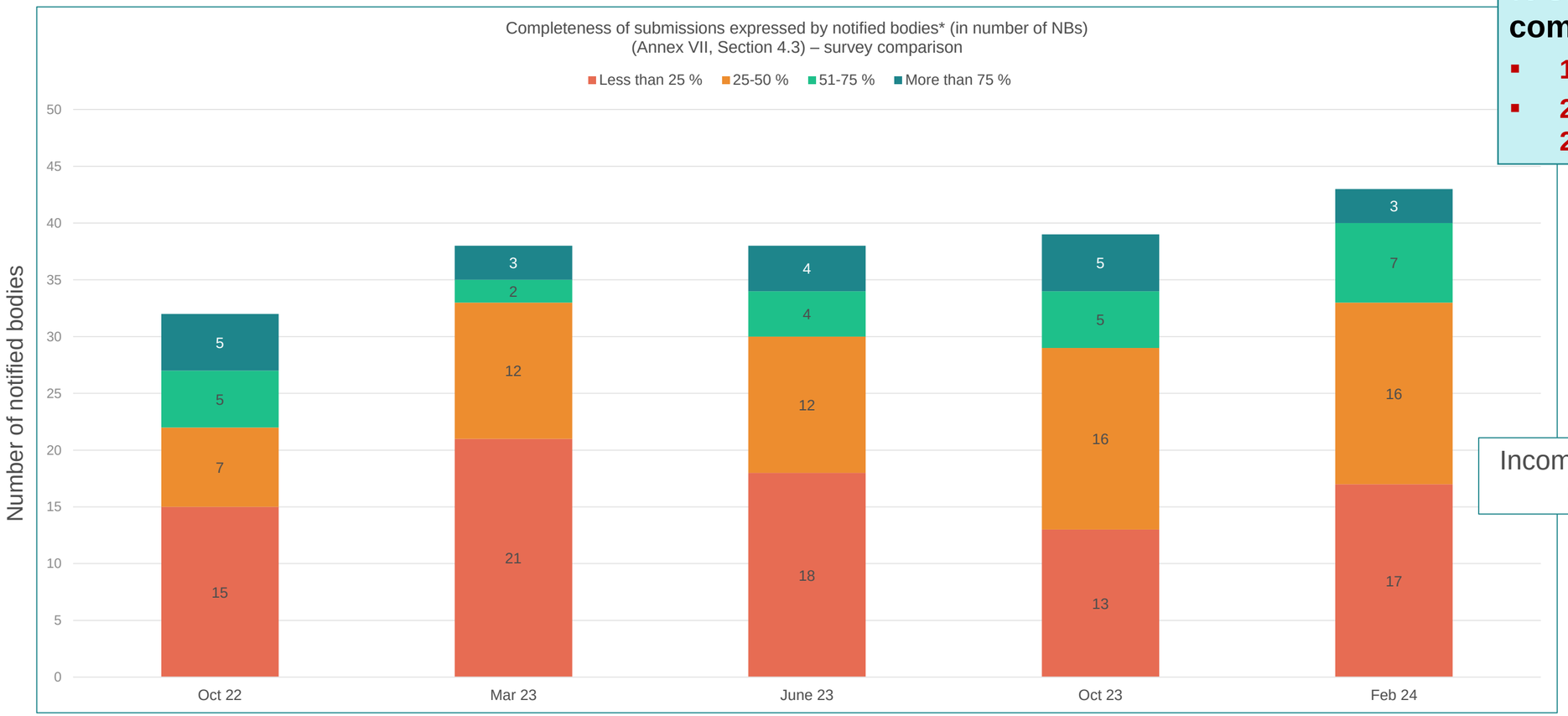



**Notes: February 2024:** Designated NBs for MD: 43; NBs that included Annex XVI products in the numbers provided: 20

* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

- Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one
- **Applications filed**: This number includes **all applications filed (syn. lodged) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up 29/02/2024) under the MDR.

# Completeness of submissions




**% of submissions with completeness rate > 50%**

- **13% (of NBs) in March 2023**
- **23% (of NBs) in February 2024**

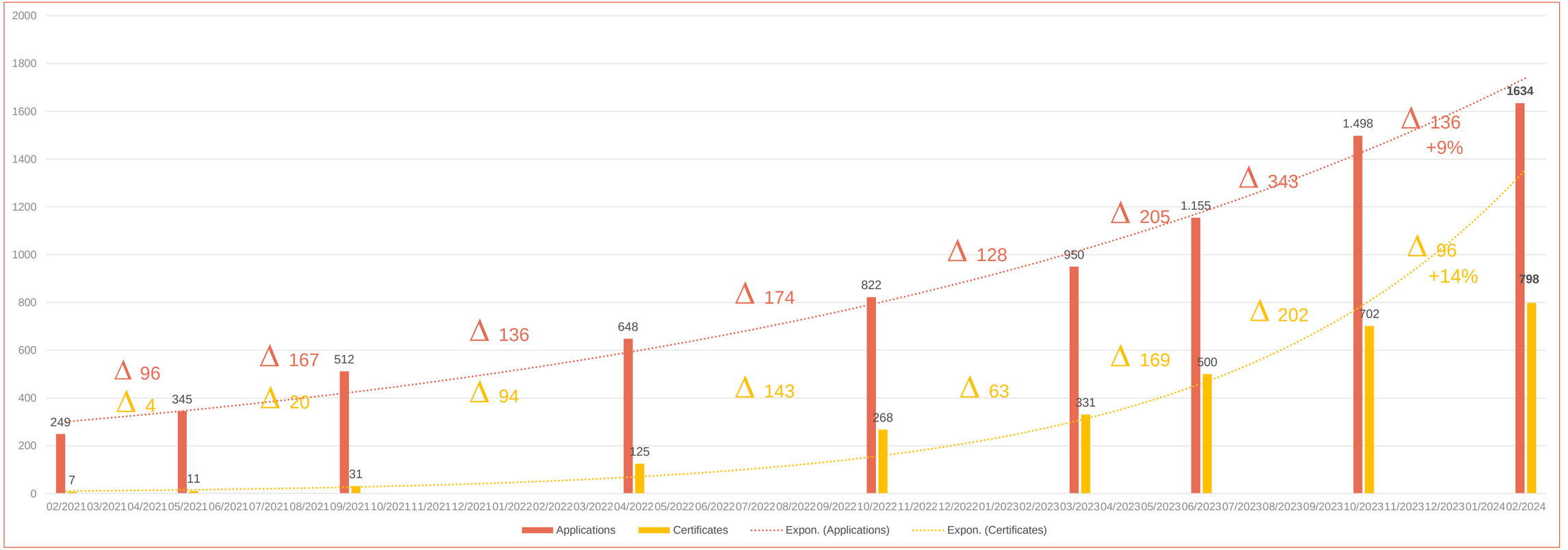
Incomplete submissions remain high*

*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

# IVDR applications lodged and certificates issued

IVD

**February 2024**
**IVDR Applications: 1.634**
**IVDR Certificates: 798**




**Notes:** Designated NBs for IVDR: 12

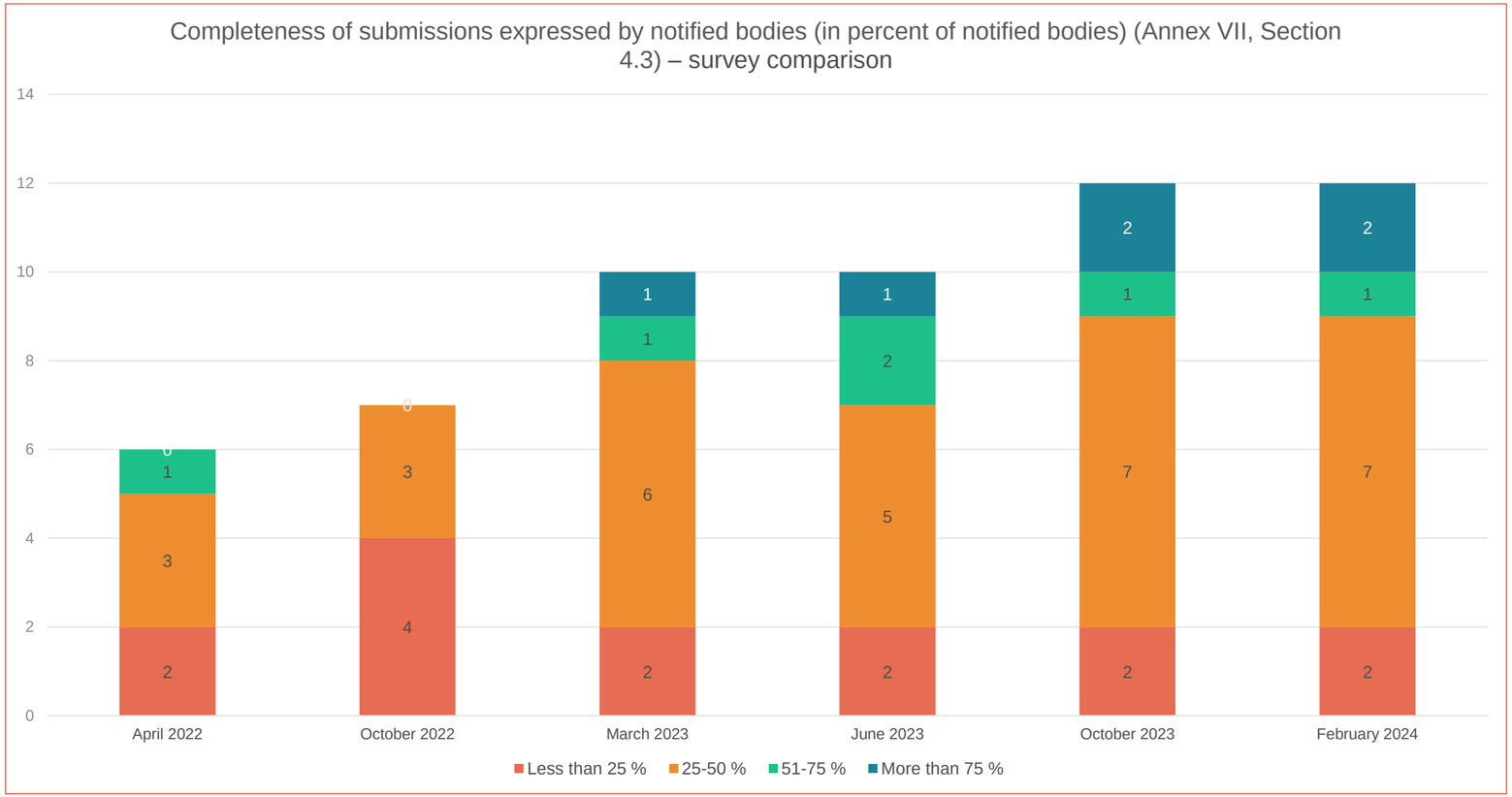
- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- **Applications lodged**: This number includes **all applications lodged (syn. filed) so far** according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up to 29/02/2024) under the IVDR.



European Commission

IVD

# Completeness of submissions




**% of submissions with completeness rate > 50%:**
**for 3 out of 12 NBs in February 2024**

Submissions largely incomplete*

* Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information



European Commission

# Survey with manufacturers (MF) and authorized representatives (AR)


Online survey conducted 30/11/23-31/01/24
**658 replies** considered for data analysis

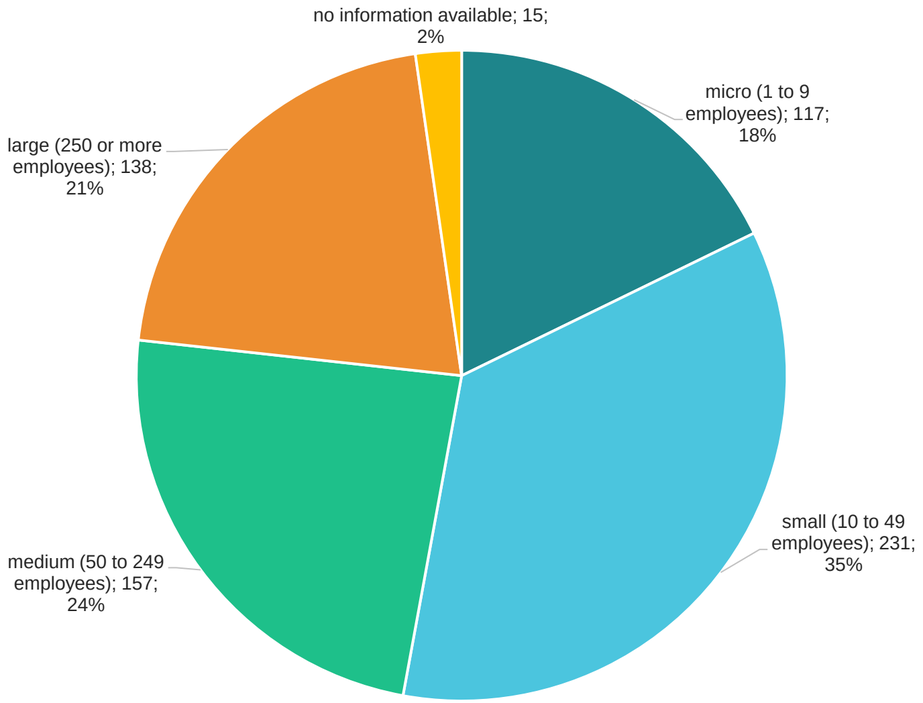
Publication foreseen for next week!

# Responses to 1st MF/AR survey by size of legal entity of organisation (globally)

About

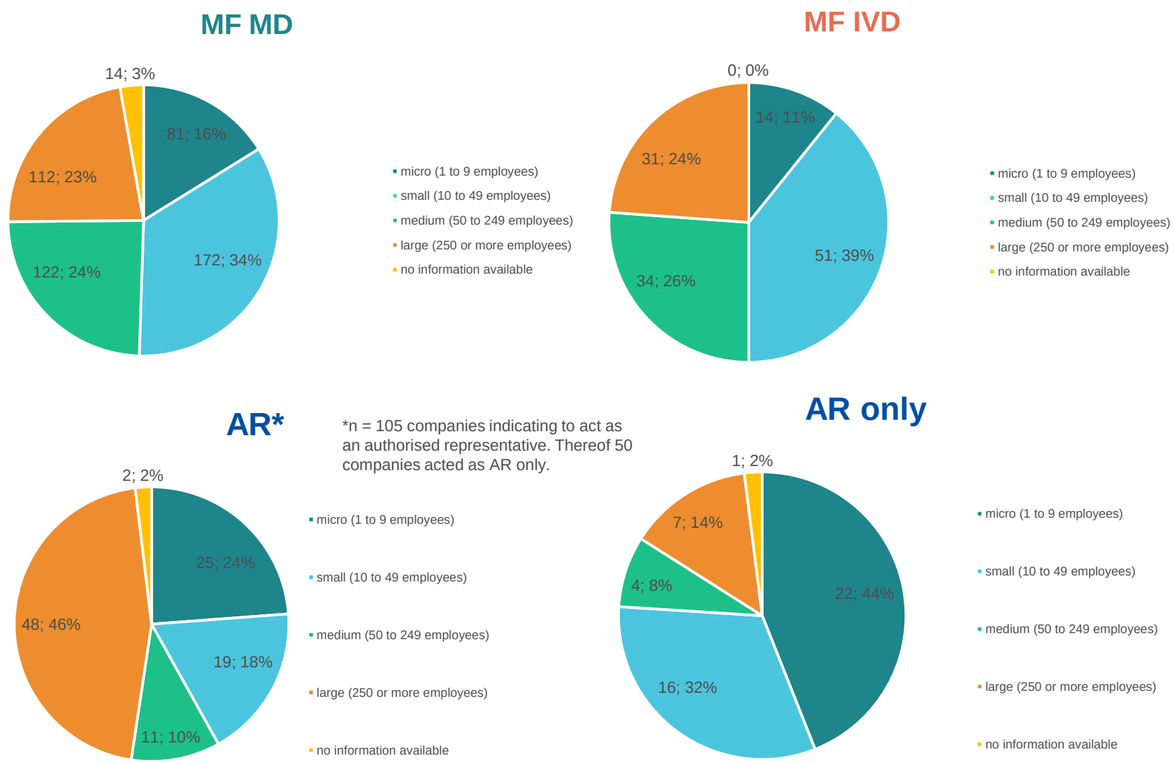
## 77% of the responding companies are **SMEs**
(micro, small and medium organisations;
1 to 249 employees)

n = 658 companies participating in the survey




## The MFs are mainly SMEs.

Company size by role (multiple choice)



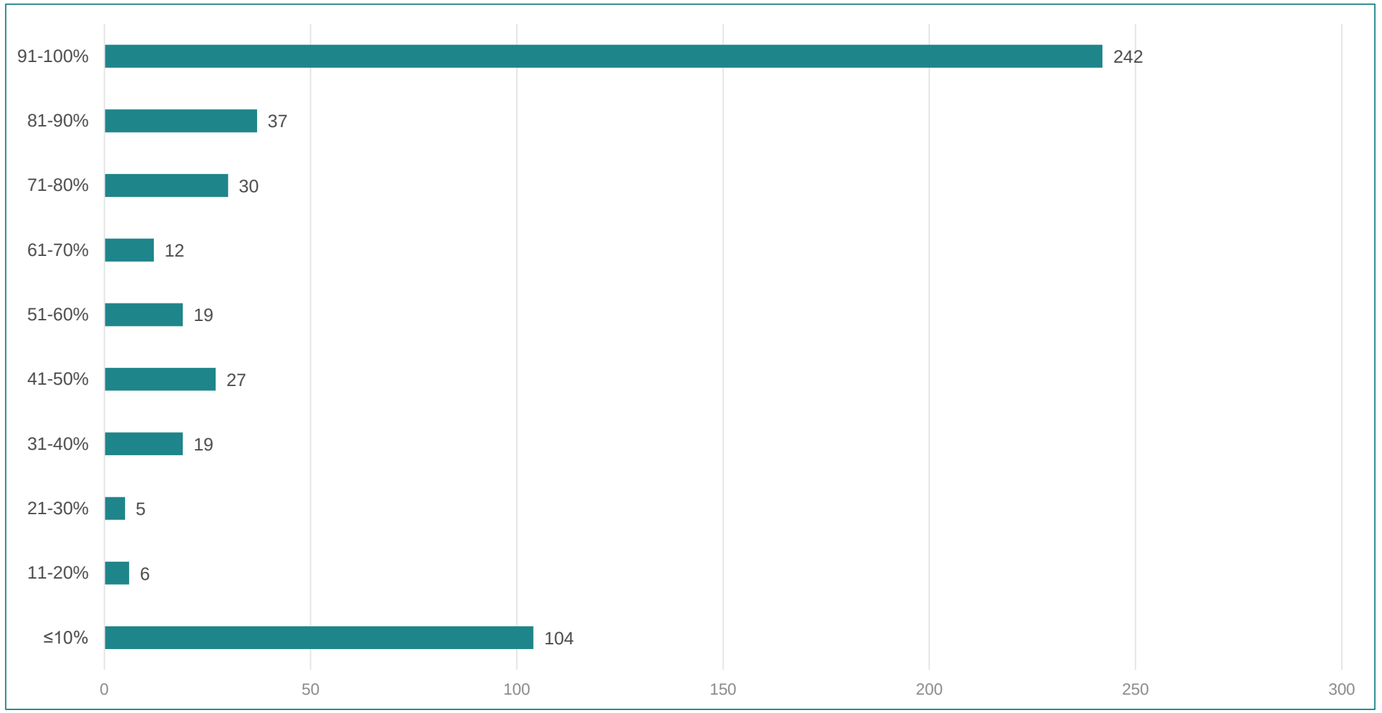
# Details on AIMDD/MDD devices transition status to MDR (1)

MD

Total responses from 501 MFs for MDs

Some companies do not aim achieving 100% - see reasons why on the next slide

## Percentage of MDs already transferred or planned to be transferred by number of MFs




Number of MFs of MDs (n = 501)

- Around half of the MFs of MDs (242 out of 501; 48%; SMEs: 50%) indicated that 91-100% of MDs have already been transferred to MDR or are planned to be transferred
- 340 MFs (68%; SMEs: 65%) reported that more than 50% of their devices are already transferred or are planned to be transferred to MDR
- 104 out of 501 MFs of MDs (21%; SMEs: 24%) indicated that ≤ 10% of MDs are transferred or planned to be transferred to MDR



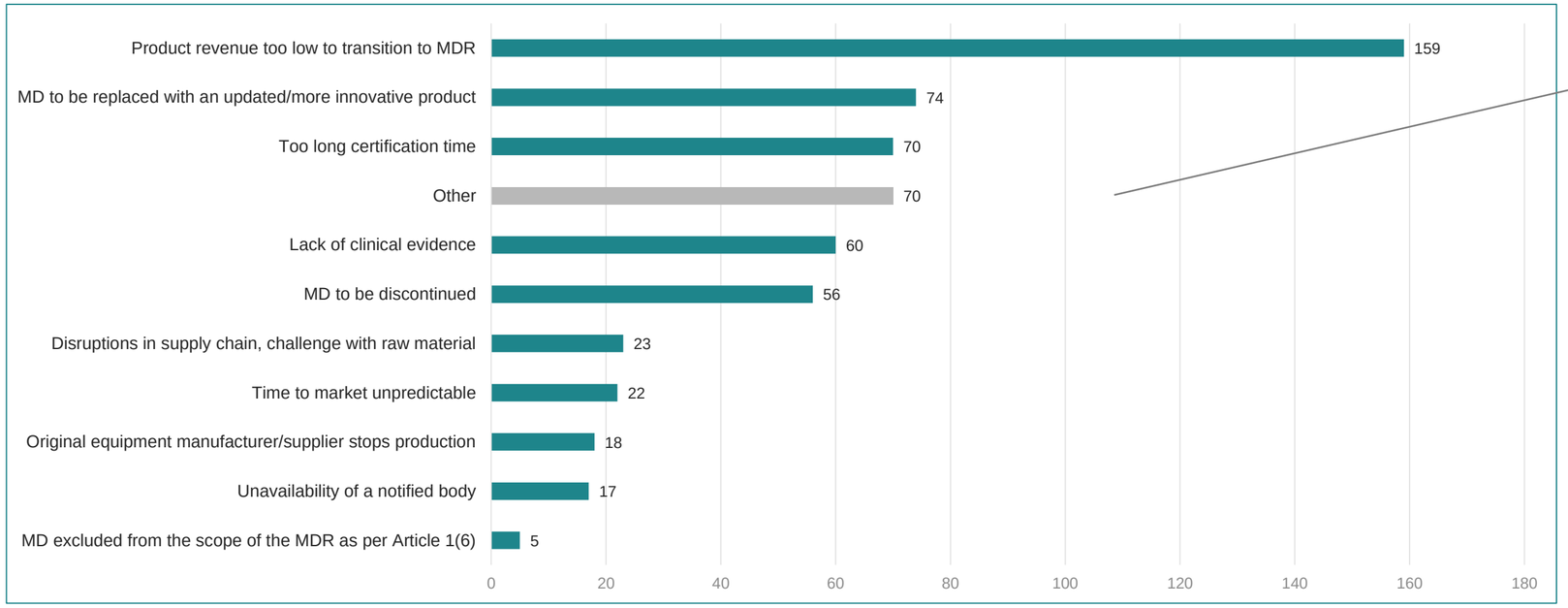
European Commission

# Details on AIMDD/MDD devices transition status to MDR (2)

**MD**

Total responses from 501 MFs for MDs

## If not all (100%) of the products have been transitioned or are planned to be transitioned to the MDR, what are the main reasons?




Number of MFs of MDs

**Some indicated 'other' reasons:**

- business and top management decision;
- strategic rationalization/simplification of the product portfolio;
- some products are not yet ready for MDR certification;
- lack of time and resources;
- too many product groups with comprehensive technical documentation, therefore step-by-step implementation;
- some devices were disqualified as medical devices per MDCG 2019-11.



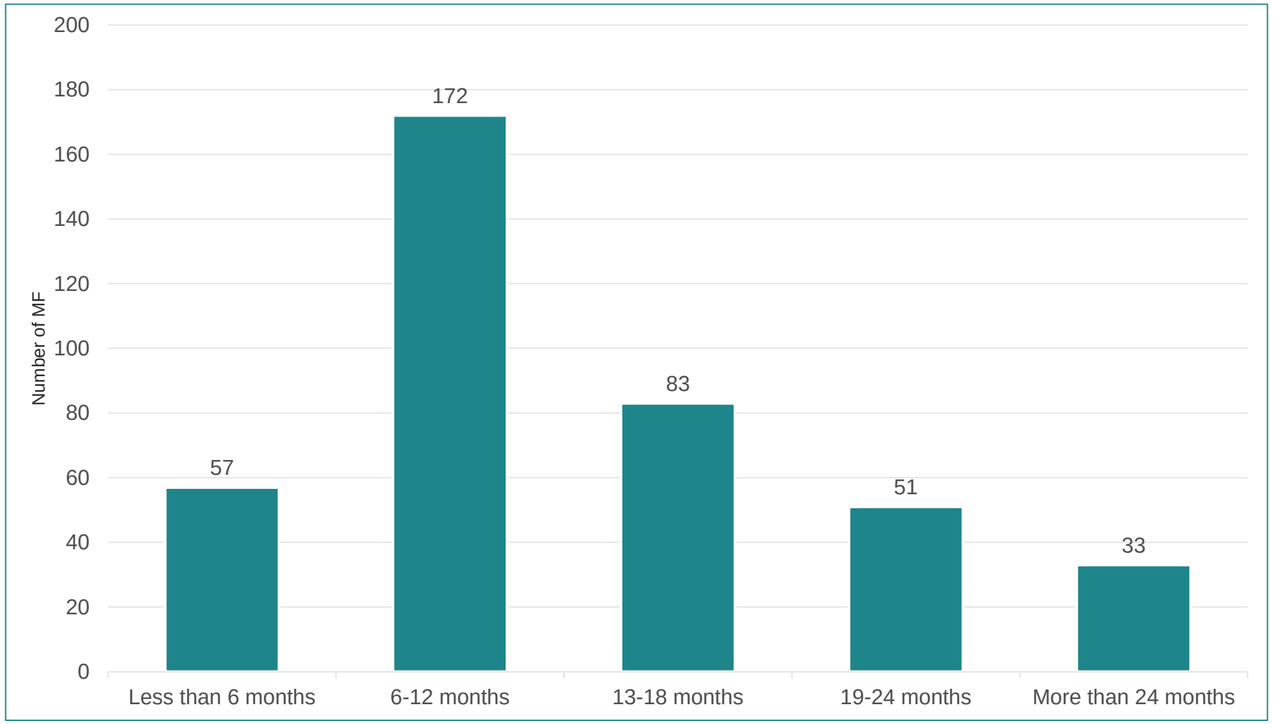
Notes: Number of mentions; Multiple answers per MF possible;
202 MFs (40%) indicated that this question is not applicable because 100% of products were already transferred

MD

# Timelines (1)

## Time to prepare an application for MDR (before submission to NB)

Total responses from 501 MFs for MDs




- **57%** of the MFs that provided information on this question indicated that it **takes less than a year** to prepare an application for MDR; f**or almost 80% less than 18 months.**

Similar % for SMEs

**Note**: Replies of 396 MD MFs
105 MFs indicated ‘no information available’

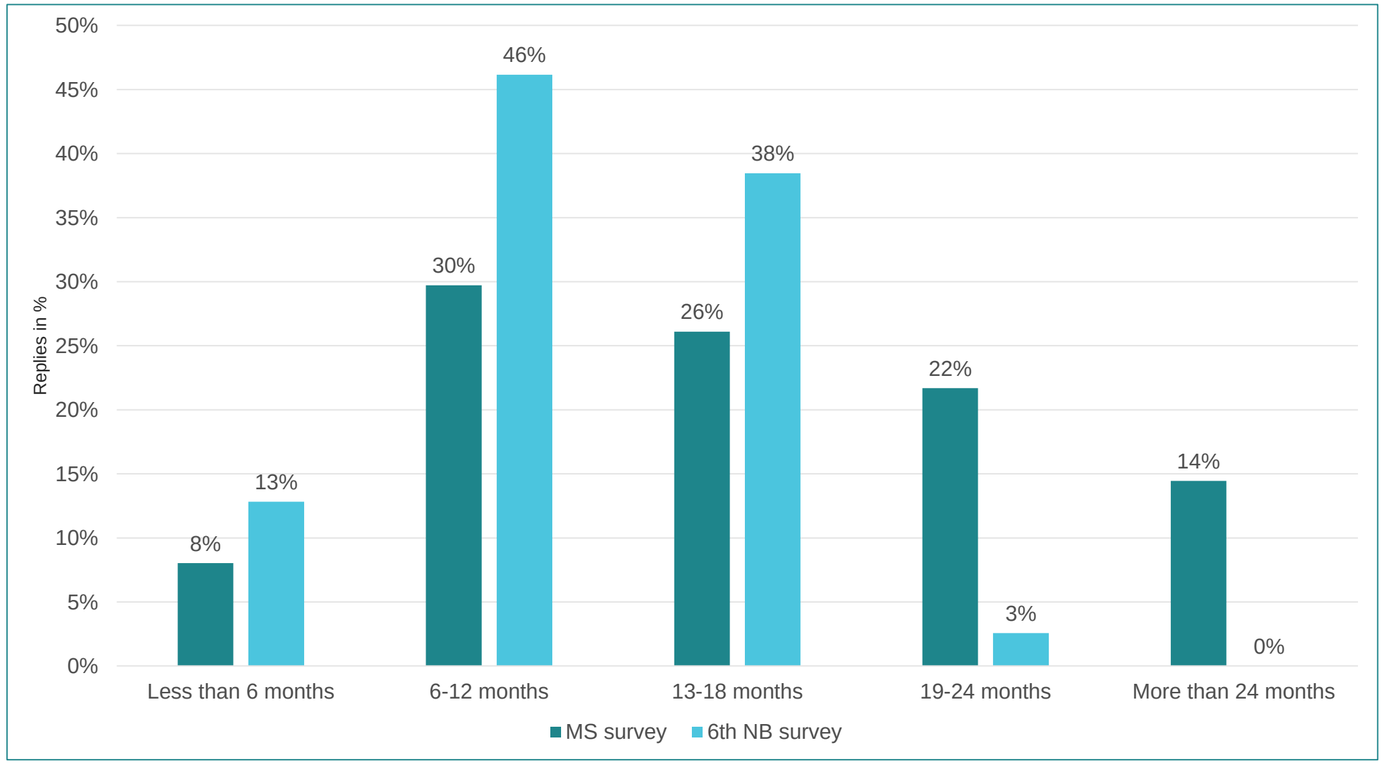


European Commission

MD

# Timelines (2)

## Time to reach/issue MDR certification for devices that only need QMS certificates (from written agreement signed to issuance)




Total responses from 501 MFs for MDs

Similar % for SMEs

**Note**: Replies of 249 MD MFs; 252 MFs indicated ‘no information available’
For comparison data of the 6th NB survey (covering the same data period until 31/10/2023):
Data of 39 notified bodies

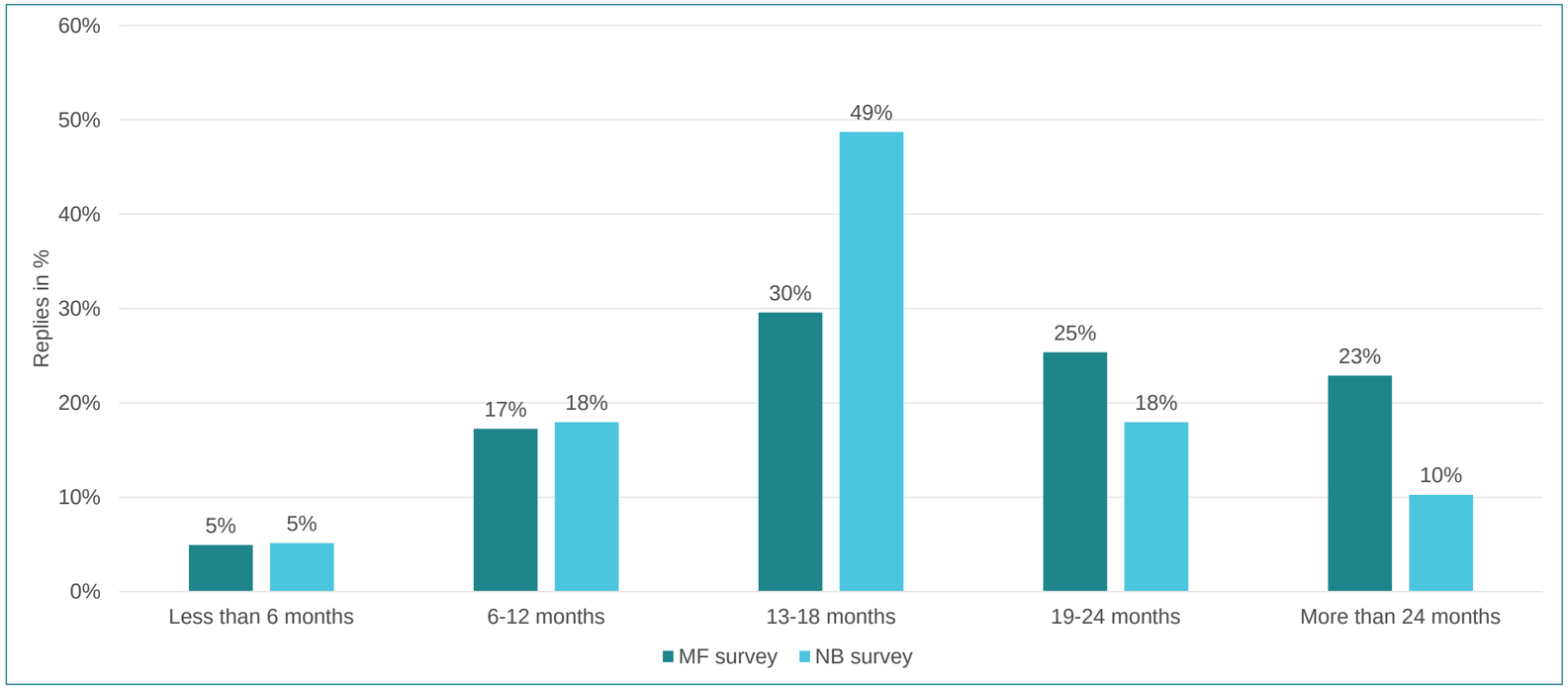


European Commission

MD

# Timelines (3)

## Time to reach/issue MDR certification for devices that need QMS and product certificates
**(from written agreement signed to issuance)**




Total responses from 501 MFs for MDs

Similar % for SMEs

**Note**: Replies of 284 MD MFs; 217 MFs indicated ‘no information available’
For comparison data of the 6th NB survey (covering the same data period until 31/10/2023):
Data of 39 notified bodies

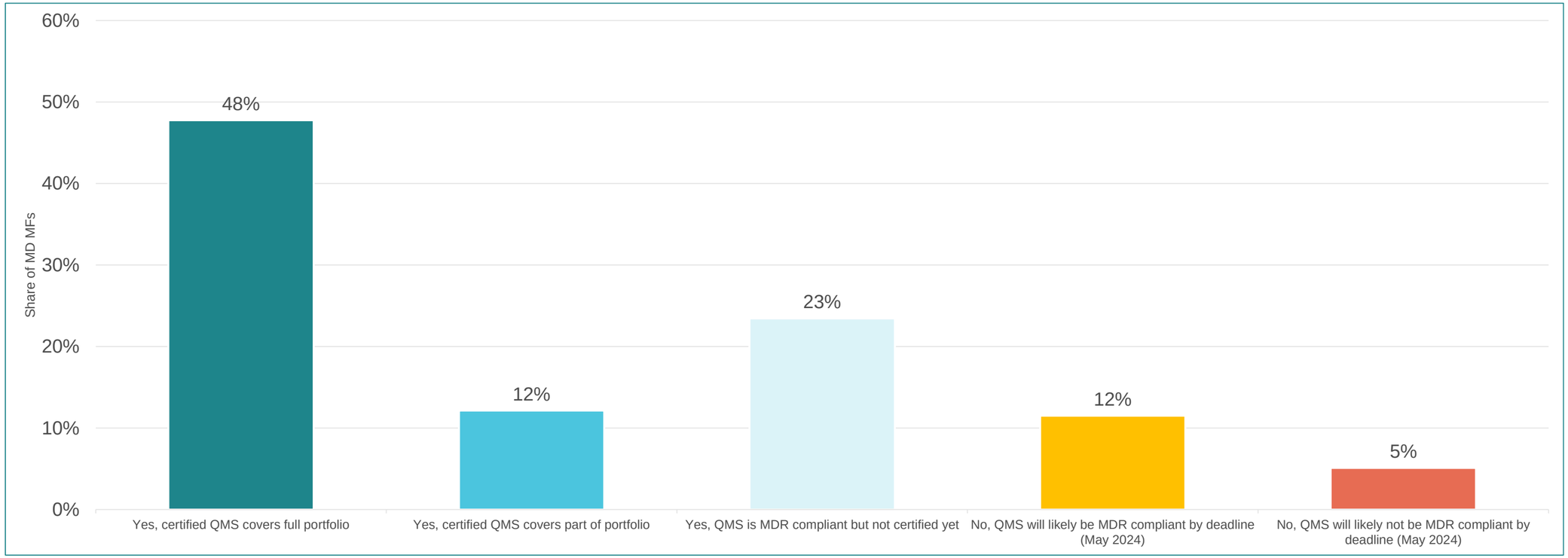


European Commission

MD

# Preparedness of manufacturers (1)

## Share of MD MF with MDR compliant QMS (n=469)




Note: Category ‘not applicable’ selected by 32 companies is not included in this graph (e.g. their products are not available yet)

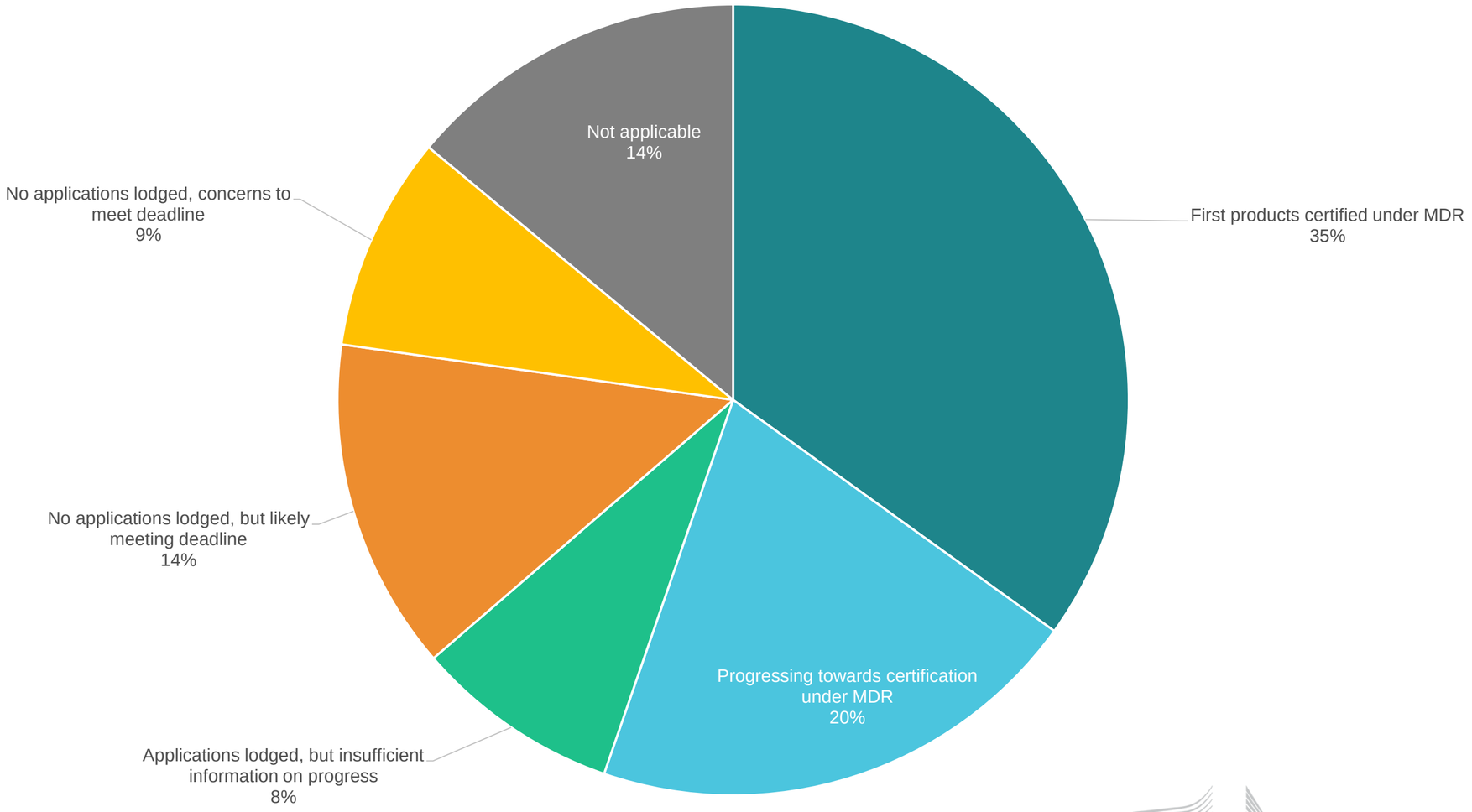


European Commission

MD

# Preparedness of manufacturers (2)

**Share of MD MF having transferred products/ technical documentation to the MDR (n=501)**






European Commission

# Contact

**Ms Friederike Windisch**
(project manager)
**Ms Nina Zimmermann**
(deputy project manager)

**medical.devices@goeg.at**

**Gesundheit Österreich GmbH (GÖG)/**
**Austrian National Public Health Institute**
Stubenring 6, 1010 Wien / Vienna

goeg.at | ppri.goeg.at

**Source:** Blätter Ahorn Herbst - Kostenloses Foto auf Pixabay - Pixabay

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# NATIONAL INITIATIVES AND BEST PRACTICES AND EU -NOBOCAP BACKBONE SERVICES

10:00-11:15

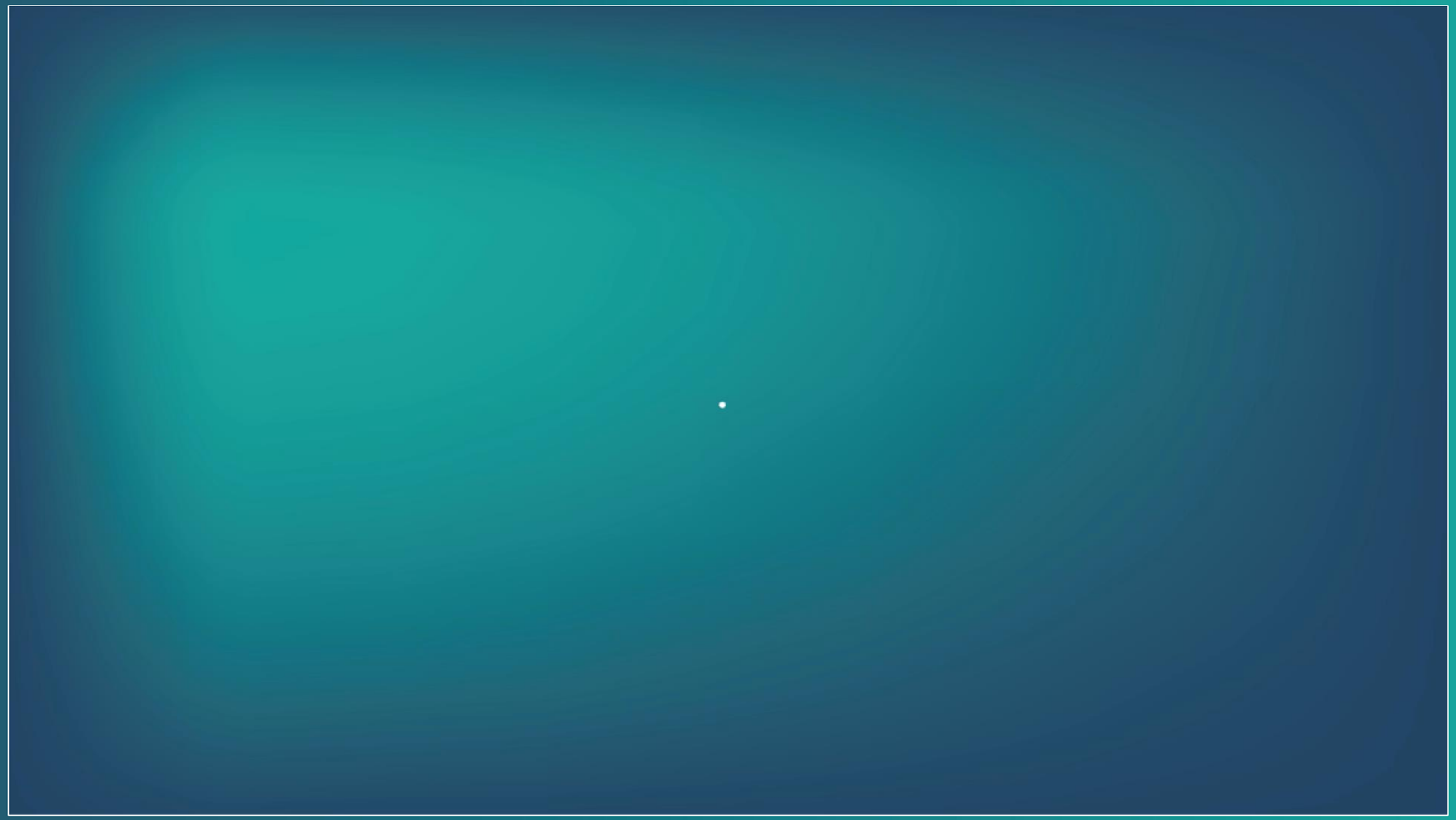
**WEDNESDAY**
**SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

Co-funded by the European Union

NoBoCap COMMUNITY



Co-funded by the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap
COMMUNITY

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**

Brussels

**#NOBOCAPSUMMIT2024**

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

# National Initiatives and Best Practices and EU

NOBOCAP COMMUNITY SUMMIT 2024

MedicalMountains

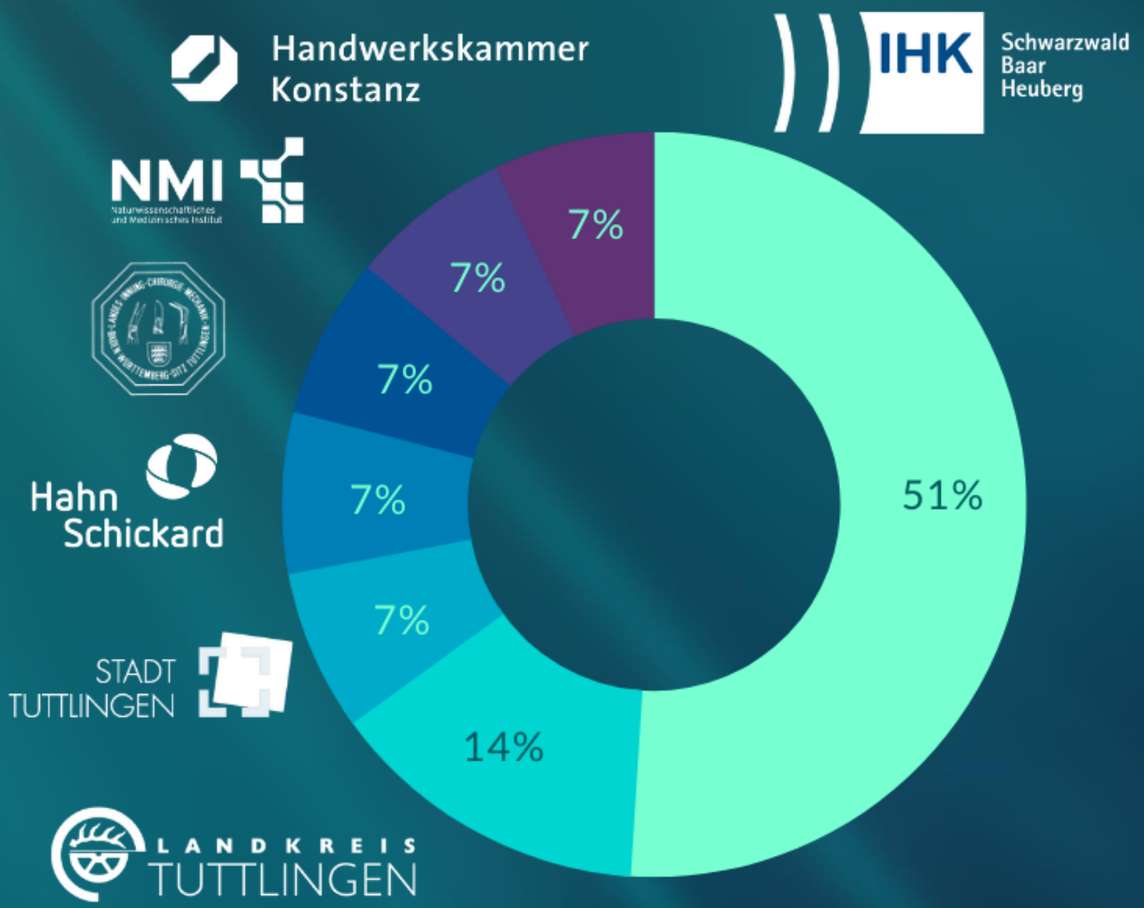
# Who we are

Experience the PULSE of medical technology

MedicalMountains GmbH is an organization that provides networking and support for all players in the medical technology industry.

- We promote dialog, combine strengths and create platforms for sharing knowledge.
- We enable cooperation and synergies through strategic and systematic coordination.

# Our shareholders




Our shareholders come from

- the public sector,
- the craft sector,
- research and science.

We act

- as an independent,
- self-financed organization
- for the entire industry.

# State of Play

97% of the companies still have **problems implementing the MDR**

The main reasons for product discontinuation are **certification costs** (91%) and **bureaucracy** (74%).

58% of companies that **discontinue their products in the EU** continue to sell these products in countries outside the EU.

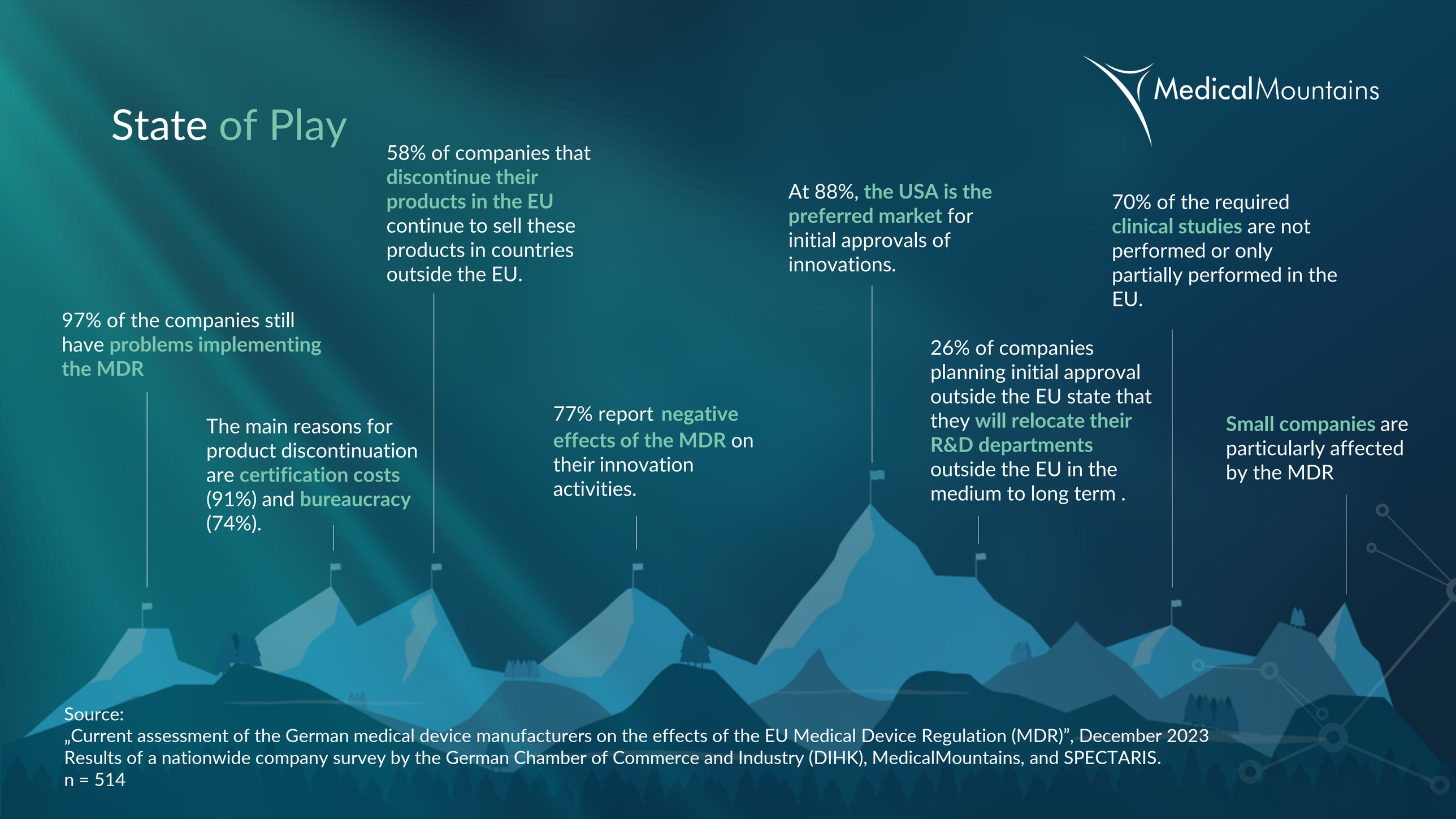
77% report **negative effects of the MDR** on their innovation activities.

At 88%, **the USA is the preferred market** for initial approvals of innovations.

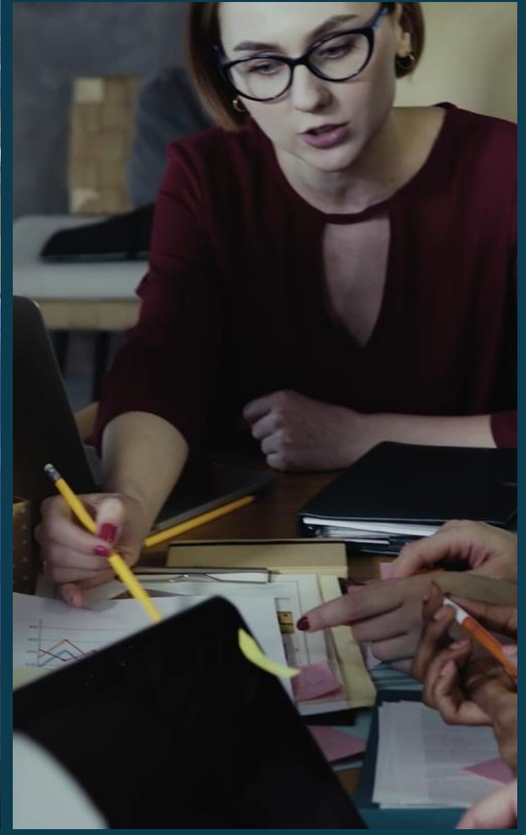
26% of companies planning initial approval outside the EU state that they **will relocate their R&D departments** outside the EU in the medium to long term .

70% of the required **clinical studies** are not performed or only partially performed in the EU.

**Small companies** are particularly affected by the MDR



Source:
„Current assessment of the German medical device manufacturers on the effects of the EU Medical Device Regulation (MDR)", December 2023
Results of a nationwide company survey by the German Chamber of Commerce and Industry (DIHK), MedicalMountains, and SPECTARIS.
n = 514

**Representing**
**INTERESTS**

e.g.
position papers

**Empowering**
**INNOVATIVE STRENGTH**

e.g.
joint projects,
events

**Expanding**
**EXPERTISE**

e.g.
> 170 seminars &
training courses p.a.

**Increasing**
**VISIBILTY**

e.g.
joint booths, talks,
podacst

**Supporting**
**IMPLEMENTATION**

e.g.
working groups,
templates

# Position paper

*Suggestions for changes by MedicalMountains GmbH for more planning security, reasonable effort, and lower costs when implementing the MDR*

- **Developed by approx. 30 manufacturers**
- **Focus on SME, but signed by non-SME as well**
- **Priority on swiftly implementable, sub-legislative measures**
- **Published in July 2024**

The three biggest problems in practice are:

- **Too much effort due to unnecessary burdens,**
- **excessive costs that are not in proportion to the product,**
- **the lack of predictability and planning security for manufacturers.**

# Key Solution approaches:

- **Unlimited validity of certification certificates**
  Abolition of the five-year re-certification cycle for medical devices of all risk classes after successful initial certification.
- **Simplified design of clinical evaluations for medical devices in low-risk classes**
  For medical devices (I, I* and some non-active products in IIa) that have been successfully marketed in the EU for five years or more, a clinical evaluation in the form of a full CEP and CER is no longer mandatory.
- **Adjustment of PMS reporting intervals**
  Adjustment of the PSUR reporting intervals for risk classes IIa to III from four years of existing market presence. The intervals will then be reduced to two years for risk classes IIb and III and to four years for class IIa.

# Key Solution approaches:

- **Practical application of the equivalence principle and “proven technologies“**
  An equivalence assessment must remain feasible even without a contract between competitors. In this context, more clarity must also be created as to what is meant by “well-established technologies” and “similar”.
- **Lean processes through electronic instructions for use and reduced mandatory languages**
  Sustainable relief in terms of time, costs, and resources can be achieved through eIFU and a reduction in the variety of languages within the EU.
- **Digitization of EU approval and abolition of national databases**
  Uniform digitized procedures are needed between manufacturers and notified bodies as well as the elimination of the obligation to fill national databases as soon as the corresponding EUDAMED modules become mandatory.

# Key Solution approaches:

- **Introduction of a "total cost" model and binding deadlines for notified bodies**
  The total costs for the compliance assessment procedure and other procedures are agreed in advance in the form of a comparable "total cost" model and are based on EU-wide specifications, as are the processing deadlines.
- **Establishment of a central MDR office at the EU level**
  The MDR office drives the harmonization of MDR requirements among the Notified Bodies, the Member States, and the companies and solves issues in a uniform manner.

The three biggest questions have to be answered:

- **Where should innovations in the field of medical devices take place in the future?**
- **How quickly should these advances reach patients?**
- **How resilient wants Europe to be in terms of healthcare?**

Position paper

## Suggestions for changes by MedicalMountains GmbH for more planning security, reasonable effort, and lower costs when implementing the MDR

https://medicalmountains.de/produkt/suggestions-for-changes-mdr/

Survey

## Current assessment of medical device manufacturers on the effects of the EU Medical Device Regulation (MDR)

https://medicalmountains.de/produkt/german-manufacturers-eu-mdr/

# Keep in touch

Experience the PULSE
of medical technology

Meinrad Kempf
Public Relations & Projects
+49 7461 969721-8
kempf@medicalmountains.de

MedicalMountains GmbH
Katharinenstraße 2 | 78532 Tuttlingen
www.medicalmountains.de

MedicalMountains

Newsletter

Podcast MedTalk ON AIR

LinkedIn

Instagram

Videos

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# BREAK PARTNERS & EXHBITION

## 11:15-11:45

Co-funded by the European Union

**WEDNESDAY SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# A CHANGING EU REGULATORY ENVIRONMENT – LOOKING AT HORIZONTAL LEGISLATION AFFECTING THE MEDICAL DEVICES SECTOR AND INNOVATION ACCESS PATHWAYS IN PARTICULAR

11:45-12:30

**WEDNESDAY**
**SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

Co-funded by the European Union

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# THE CHANGING REGULATORY ENVIRONMENT FOR MEDICAL DEVICES, IVD, DIGITAL-AI AND COMBINATION PRODUCTS BY EUROPEAN COMMISSIO

**Flora Giorgio**
EUROPEAN COMMISSION
Head of unit MDR/IVDR

Co-funded by the European Union

**WEDNESDAY**
**SEPTEMBER 25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# IN DEPTH EVALUATION OF EU ENVIRONMENTAL AN DUE DILIGENCE LEGISTION IMPACTING MEDICAL TECHNOLOGY

**Stefan Berggren**
MEDICAL PRODUCT AGENCY SWEDEN
Head of unit for Sustainability and Environment

Co-funded by the European Union

**WEDNESDAY**
**SEPTEMBER 25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# Your questions?

SLIDO.COM

Join Slido at

https://app.sli.do/event/7YbioqsA2WMWb14SeCfqPj

Co-funded by the European Union

WEDNESDAY
SEPTEMBER 25, 2024
Brussels

# A changing EU regulatory environment – Looking at horizontal legislation affecting the medical devices sector and innovation access pathways in particular

**Flora Giorgio**
European Commission
Directorate-General for Health and Food Safety (DG SANTE)
Unit D.3 – Medical Devices

# Health Technology Assessment Regulation

European Commission

# Regulation on Health Technology Assessment (HTA)

- Adoption 15/12/2021; in force 11/01/2022; in application **12/01/2025**
- Establishing: **a support framework and procedures** for cooperation of Member States on health technologies at Union level; **a mechanism for the submission of evidence** for joint clinical assessments only once at Union level; **common rules and methodologies** for joint clinical assessments.
- Vision: improve **patient access** to innovative technologies, strengthen the **quality** of HTA across the EU, avoid duplication and ensure **efficiency** (incl. on clinical evidence generation), secure the **long-term sustainability** of EU HTA cooperation.

# HTA Regulation - Key elements

- **Joint work** at EU level limited to the **clinical aspects** of HTA:
  - **Joint Clinical Assessment (JCA)** -> assessment of the relative effectiveness and relative safety of a product compare to other products available on the market
  - **Joint Scientific Consultation (JSC)** -> advice to manufacturers on their plan to generate clinical data in view of future JCA
- Joint work **carried out by Member State HTA bodies** with input of **individual experts**
- **Member States** remain responsible for:
  - Drawing **conclusions on added value** for their health system
  - Taking decisions on pricing & reimbursement
- Ensure **use of joint work in national HTA processes**

# MDs and IVDs in scope of **JCA**
## Articles 7(1) and 7(4) of the HTA Regulation

Class III and class IIb **MDs** and class D **IVDs** that received an **expert panel opinion/views** AND subject to **selection** based on criteria listed in Article 7(4) of the HTA Regulation

- **JCA selection criteria**: a) unmet medical needs; b) first in class; c) potential impact on patients, public health or healthcare systems; d) incorporation of software using artificial intelligence, machine learning technologies or algorithms; e) significant cross-border dimension; f) major Union-wide added value.

European Commission

# MDs and IVDs in scope of **JSC**
## Articles 16(2) and 17(3) of the HTA regulation

**MDs and IVDs, likely to be subject to JCA** and where the clinical studies and clinical investigations are still in the planning stage

- **JSC Selection criteria**: a) unmet medical needs; b) first in class; c) potential impact on patients, public health or healthcare systems; d) significant cross-border dimension; e) major Union-wide added value; f) Union clinical research priorities

- Possibility for the manufacturer to request that the JSC takes place **in parallel of an expert panel's scientific advice**

# Artificial Intelligence Act (AI Act)

European Commission

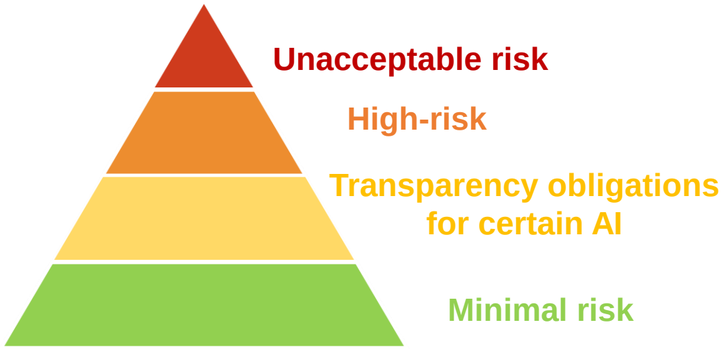
# The Artificial Intelligence Act

- **Regulation (EU)2024/1689 (AI Act)** of 13 June 2024 was published in the Official Journal of the European Union on 12 July 2024.
Regulation - EU - 2024/1689 - EN - EUR-Lex (europa.eu)

- **Horizontal EU legislation laying down uniform rules for AI in the EU market**
  - "Classic" **internal market product safety** rules applicable to the placing on the market, putting into service and use of AI systems
  - Two main objectives:
    - address **risks to health, safety and fundamental rights**
    - **create a single market for trustworthy AI in EU**

# The Artificial Intelligence Act

- **Innovation-friendly, agile and risk-based**
  - **No overregulation**: designed to intervene only where strictly needed following a **risk-based approach**
  - Addresses also risks of **generative AI** through **transparency obligations** for operators
  - Supports innovation through **regulatory sandboxes**
  - Provide **legal certainty** to operators and stimulate **trust** in the market




- **Creates a level playing field for EU and non-EU players**

  Applicable independent of origin of producer or user

European Commission

# Interplay between MDR/IVDR and AIA Requirements for high-risk AI – including medical devices (Title III, chapter 2)

COM will carefully consider the requirements for medical devices set out in the AI Act and build on the existing regulatory system of MDR/IVDR Q&A on the interplay MDR/IVDR with AI Act early 2025

Establish and implement an iterative **risk management** process (identify & mitigate risks)

- Use high-quality **training, validation and testing datasets**
  Implement **data governance procedures**
- Establish **documentation** in Annex IV and design the system with **logging** features (traceability & auditability)
- Ensure appropriate degree of **transparency and interpretability** of the system by design & provide users with **information** (on how to use the system, its capabilities and limitations, potential risks etc.)
- Enable **human oversight** aimed to minimize residual risks (measures built into the system and/or to be implemented by users)
- Ensure **robustness**, **accuracy** and **cybersecurity** throughout the lifecycle

European Commission

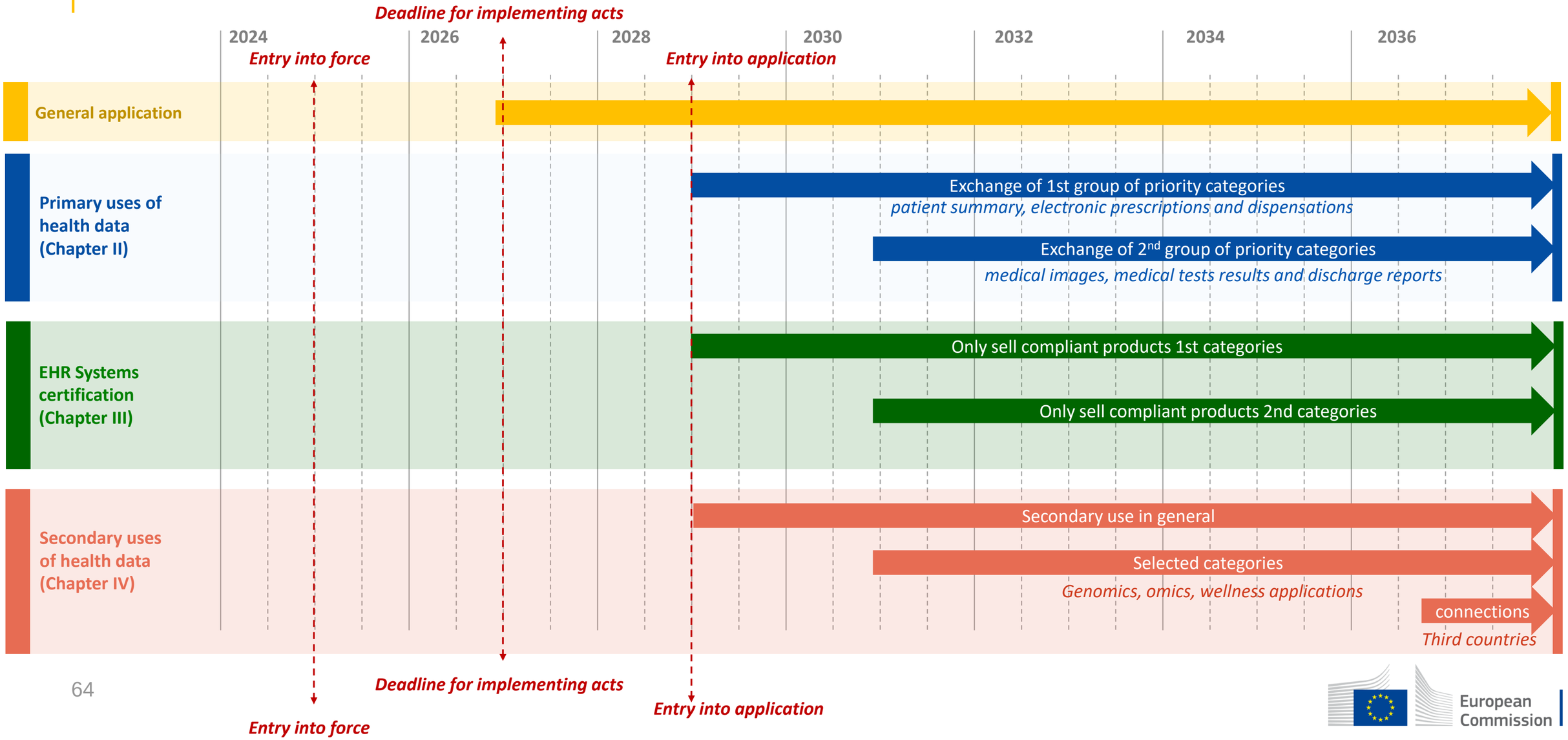
**NB! Harmonised technical standards** developed by ESOs will support providers to demonstrate compliance.

# European Health Data Space (EHDS)

European Commission

Timelines are indicative.

# Regulatory implementation of the EHDS






European Commission

# EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. Secondary use = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems, supporting both primary and secondary use.

# Interaction with other relevant product rules

- Some EHR systems may have additional functions that make them also qualify as e.g. a medical device/IVD (Article 14 EHDS)
  - Both sets of requirements (MDR/IVDR and EHDS) apply
- Medical devices, in-vitro diagnostic medical devices, and high-risk AI systems (which are not medical devices at the same time) that claim interoperability with EHR systems:
  - Have to comply with **common specifications from the EHDS Regulation** Art. 23 (4) EHDS, Annex II
    → these will still be developed via implementing act

# Thank you!

*Contacts:*

European Commission - Directorate-General for Health and Food Safety (DG SANTE)
*Unit D.3 Medical Devices*
SANTE-MED-DEV@ec.europa.eu



European Commission

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

# NoBoCap Summit - 25 September 2024

**Stefan Berggren, Swedish MPA**

**-Director, Environment and Sustainability, and Swedish Knowledge Centre for Pharmaceticals in the Environment**

**-Chair of the European Working Group on PiE**

**-Co-lead of the European Task Force on MD and environment**

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# European Environmental Policy

- The 8th Environment Action Programme (EAP) guide European environmental policy
  - Entered into force on 2 May 2022, as the EU's legally agreed common agenda for environment policy until 2030
- First program set already in the 1970s
- EU’s long-term vision to 2050 of living well and within planetary boundaries. It sets out priority objectives for 2030 and the conditions needed to achieve these. Building on the European Green Deal, the action program aims to speed up the transition to a climate-neutral, resource-efficient economy, recognizing that human wellbeing and prosperity depend on healthy ecosystems
- The 8th EAP calls for active engagement of all stakeholders, to ensure that EU climate and environment laws are effectively implemented. It forms the EU’s basis for achieving the United Nation’s **2030 Agenda** and its **Sustainable Development Goals**


SUSTAINABLE DEVELOPMENT GOALS
1 NO POVERTY
2 ZERO HUNGER
3 GOOD HEALTH AND WELL-BEING
4 QUALITY EDUCATION
5 GENDER EQUALITY
6 CLEAN WATER AND SANITATION
7 AFFORDABLE AND CLEAN ENERGY
8 DECENT WORK AND ECONOMIC GROWTH
9 INDUSTRY, INNOVATION AND INFRASTRUCTURE
10 REDUCED INEQUALITIES
11 SUSTAINABLE CITIES AND COMMUNITIES
12 RESPONSIBLE CONSUMPTION AND PRODUCTION
13 CLIMATE ACTION
14 LIFE BELOW WATER
15 LIFE ON LAND
16 PEACE, JUSTICE AND STRONG INSTITUTIONS
17 PARTNERSHIPS FOR THE GOALS

# UN has 17 Sustainable Development Goals (SDGs)

## connecting economy, society and biosphere


Credit: Azote Images for Stockholm Resilience Centre, Stockholm University

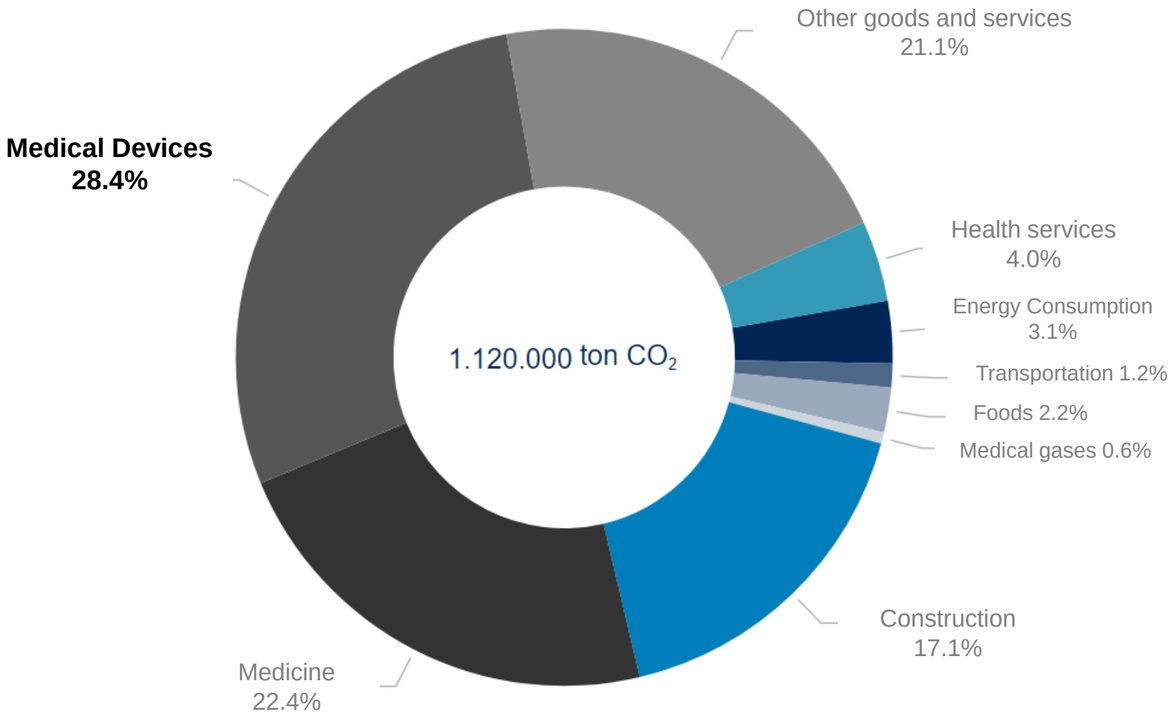
Information on Sustainable Development Goals (SDGs): www.un.org/sustainabledevelopment/
www.un.org/sustainabledevelopment/wp-content/uploads/2019/01/SDG_Guidelines_AUG_2019_Final.pdf

# European Environmental Policy

- Green Deal - The European Green Deal - European Commission (europa.eu)
- Circular economy action plan - European Commission (europa.eu)

- To make goods on the EU market more environmentally friendly, recyclable, and energy efficient throughout their whole lifecycle

# Task Force on MD and environment (from DK)




The distribution of the climate footprint in the Capital Region of Denmark
Source: https://flis.regionh.dk/reports/powerbi/Center%20for%20Ejendomme/Klima-%20og%20milj%C3%B8regnskab%202023?rs:Command=Render&rc:Toolbar=false

A sector with a considerable impact on the environment

An opportunity to focus on possibilities to strengthen the green obligations within MDR/IVDR

A step to simplify environmental considerations for the sector

# Task Force on environment

A sector with a considerable impact on the environment

An opportunity to focus on possibilities to strengthen the green obligations within MDR/IVDR

To simplify environmental considerations for the sector

To align and harmonize MD and IVD regulation with complex horizontal legislation at EU level

To undertake a proactive approach to new environmental legislation with future consequences for the sector

# Task Force - Organisation and work

## Mechanism for monitoring and sharing knowledge amongst MSs on:

- **Mapping and monitoring**
  - EU horizontal legislation on environmental nature/matter that is applicable to MDs and IVDs
  - Assess whether horizontal requirements on environmental nature/matter can affect availability and the safety and performance of MDs and IVDs
  - Propose solutions to the MDCG to tackle identified potential issues in interplay between relevant horizontal legislation on environmental matter and MDR/IVDR

# Task Force - Organisation and work cont.

**Contributing to environmental sustainability**

- Make use of MDR and IVDR to contribute to environmental sustainability of medical device
- Encouraging incentives in the system for more innovative and environmentally friendly solutions
- Knowledge sharing on relevant topics – e.g.
  - ✓ Experiences with reprocessing of single-use devices;
  - ✓ Opportunities and challenges with using electronic instructions for use (E-IFU)
- **Members**
  - DK and SE co-chair - DE, DK, ES, FR, FI, NL, PT, SE, COM and TR are members, at present open for new members

# EU’s environmental and due diligence legislation impact on medical devices and medical technology – some examples

- **Packaging and Packaging Waste Directive**:

This directive aims to reduce the environmental impact of packaging waste. Medical device manufacturers must ensure that their packaging is minimal, recyclable, and made from sustainable materials

- **Corporate Sustainability Due Diligence Directive**:

This directive requires large companies to audit their supply chains to identify and address human rights and environmental issues. Companies must demonstrate adherence to the standards across their operations and global value chains

- **Environmental Due Diligence**:

Companies are required to integrate environmental considerations into their business practices, ensuring compliance with both EU and international environmental standards. This includes assessing and mitigating environmental risks associated with their products and operations

# EU’s environmental and due diligence legislation impact on medical devices and medical technology – some examples

**Eco-Design Requirements**

- Manufacturers must design products with minimal environmental impact throughout their lifecycle. This includes considerations for energy efficiency, material selection, and end-of-life disposal

**RoHS Directive**

- The Restriction of Hazardous Substances (RoHS) Directive restricts the use of specific hazardous materials found in electrical and electronic products, including medical devices. Compliance requires due diligence to ensure that none of the components exceed the allowed thresholds for these substances

**And much more!**

# Regulations concerning MD and M technology

- Battery Regulation
- CLP Regulation
- Due Diligence
- GPSR
- Biocidal Products Regulation
- POP Regulation
- REACH Regulation
- RoHS Directive
- WEEE Directive
- Ecodesign Directive
- Packaging Regulation
- Waste Directive
- Right to repair
- Conflict Minerals Regulation
- Single-Use Products Regulation
- CSDDD
- EDD

# Regulation - responsible agencies in Sweden

| Swedish Agency | Regulation | Scope |
|---|---|---|
| Energy Authority Agency | WEEE-direktivet | Omfattar avfall som utgörs av eller innehåller elektrisk och elektronisk utrustning |
| | Batteriförordningen | Innehåller regler om förbud mot att släppa ut batterier och ackumulatorer på marknaden om de innehåller över en viss halt av tungmetallerna kvicksilver och kadmium |
| | Ekodesigndirektivet | Krav på energiprestanda hos produkter och förbud mot de mest energi- och resurskrävande produkterna på EU-marknaden |
| Chemical Agency (KEMI) | Reach-förordningen | Inklusive bestämmelser om ftalater, mikroplaster, cykliska siloxaner och PFAS |
| | CLP - Classification, Labelling and Packaging | Märkningskrav för kemiska ämnen och blandningar |
| | RoHs-directive | Restriction of the use of certain Hazardous Substances in Electrical and Electronic Equipment (kvicksilver, kadmium, bly,mm) |
| | POP-förordningen | Krav på långlivade organiska föroreningar som flamskyddsmedel och PFOS |
| Medical Products Agency | MDR/IVDR | Medicintekniska produkter och in vitro-diagnostiska produkter |
| Environmental Protection Agency | Avfallsdirektivet | SCIP - krav på anmälan av särskilt farliga ämnen i varor olämpligt för återvinning |
| | Förpackningsförordningen | Innehåller bestämmelser om ett utökat producentansvar |
| | Engångsproduktsförordningen | Förbud mot att på den svenska marknaden släppa ut vissa engångsprodukter |
| Agency of Geological Survey | Konfliktmineraler | Konfliktmineraler |

# Environmental Due Diligence (EDD)

- **Focus**: Primarily on environmental impacts
- **Scope**: Ensures that companies assess and mitigate environmental risks and impacts associated with their operations and projects. This includes pollution, resource depletion, and biodiversity loss
- **Application**: Often applied during mergers and acquisitions, project financing, and other business transactions to identify potential environmental liabilities

# Corporate Sustainability Due Diligence Directive (CSDDD)

- **Focus**: Broader scope covering both human rights and environmental impacts
- **Scope**: Requires companies to identify, prevent, mitigate, and account for adverse human rights and environmental impacts in their own operations, their subsidiaries, and their value chains
- **Application**: Applies to large companies operating in the EU, including non-EU companies with significant activities in the EU. It mandates adoption of transition plans for climate change mitigation aligned with the 2050 climate neutral objective of the Paris Agreement on climate

# Summary EDD and CSDDD

- EDD is more narrowly focused on environmental issues,
- CSDDD encompasses a wider range of sustainability concerns, including human rights and environmental impacts, and imposes more comprehensive due diligence obligations on companies

# Thank you for your attention!

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# LUNCH BREAK PARTNERS & EXHBITION

## 12:30-13:15

**WEDNESDAY SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

Co-funded by the European Union

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# EU REGULATION – A CHALLENGING ENVIRONMENT - ROAD AHEAD FOR MDR/IVDR – EU POLICY AND EU INITIATIVES

13:15-14:30

Co-funded by the European Union

**WEDNESDAY SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# KEY NOTE : EU INITIATIVES TO FOSTER AN INNOVATION SUPPORTIVE REGULATORY ENVIRONMENT

**Flora Giorgio**
EUROPEAN COMMISSION
Head of unit MDR/IVDR

Co-funded by the European Union

**WEDNESDAY**
**SEPTEMBER 25, 2024**
Brussels

# EU INITIATIVES TO FOSTER AN INNOVATION SUPPORTIVE REGULATORY ENVIRONMENT

**Flora Giorgio**
European Commission
Directorate-General for Health and Food Safety (DG SANTE)
Unit D.3 – Medical Devices

# Political Guidelines for the next European Commission 2024-2029

- Make business easier (p. 6)

Priority will be given to simplification of legislation to clear overlaps and contradictions, **especially for SMEs**, in an effort to reduce red tape and reporting obligations. In this context, the Commission will propose the introduction of a new EU wide legal status (28th regime) to provide companies with a “simpler, harmonised set of rules in certain areas” to **support innovative companies grow**

Commission President on 18/9 in the EP said**: *“This Commission is very committed to competitiveness, decarbonization and digitalization.”***

European Commission

# Regulations (EU) 2017/745 and 2017/746

- (1) Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) constitute the Union regulatory framework for medical devices, other than in vitro diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which **ensures a high level of safety and health whilst supporting innovation**.
- (1) Directive 98/79/EC of the European Parliament and of the Council (3) constitutes the Union regulatory framework for in vitro diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for in vitro diagnostic medical devices which **ensures a high level of safety and health whilst supporting innovation.**

# Targeted evaluation of the regulations

Focus on:

- how the MDR/IVDR affect the availability of medical devices in the EU, in particular **devices for small patient populations (‘orphan devices’) and innovative devices**
- costs and administrative burden stemming from the implementation of the legislation, **especially for SMEs**

Evaluation to be finalised in 2025

# EU Inititatives that foster innovation

European Commission

# Scientific Advice from EMA Expert Panels (1/2)

Scientific advice from Expert panels to Manufacturers (Art. 61 (2) MDR)

- To provide advice on the development of the clinical strategy in the pre-market phase and/or proposal for clinical investigations

- Pilot started in 02/2023 and is ongoing
- **Applicants**: manufacturers/authorised representatives established in the EEA (SMEs encouraged to submit)
- **Fees:** No fees during the pilot phase

# Scientific Advice from EMA Expert Panels (2/2)

- **Selection criteria**:
  - Devices intended to benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition (e.g. “orphan devices”, devices for paediatric use)
  - Devices for unmet medical needs i.e., medical conditions that are life-threatening or cause permanent impairment of a body function AND for which current medical alternatives are insufficient or carry significant risks ( “breakthrough device” - MEDDEV 2.7/1 rev.4, Appendix 8 )
  - Novel devices with a possible major clinical or health impact
  - Aiming to represent different clinical areas and types of devices

# Structured Dialogue between manufacturers and Notified Bodies

- **Draft MDCG guidance 2019-6 Revision 5**
  (*Questions and answers: Requirements relating to notified bodies*)
  circulated to Notified Bodies and MDCG stakeholders for consultation and comments on 18 September
- New question added on **“structured dialogue”**
- Structured dialogue between manufacturer and notified body before and during the conformity assessment process aimed to enhance
  **the efficiency and predictability of the conformity assessment process**

# New Guidance on clinical evaluation of orphan medical devices (June 2024)

- MDCG 2024-10 guidance for devices intended to be used for diseases or conditions affecting only a small number of individuals each year („orphan devices“) sets out:
  - Criteria for determining an „**orphan medical device“** status under MDR
  - Guides manufacturers and notified bodies when applying **clinical evidence requirements** to help overcome some of the challenges that lead to delays in patient access to orphan devices
  - foresees possibility to seek advice from EMA expert panels on the orphan status / clinical data needed

# Establishment of a Horizon Scanning system in the area of medical devices

- **EU4Health Work Plan 2024 – start in Q1/2 2025**
- Monitor the development of new medical technologies, innovations and trends to:
  - Detect those bringing major benefit
  - Detect those bringing risks or challenging the EU regulatory system
- It will provide key input to regulators and all stakeholders (esp. Notified Bodies)
- It will enable an analysis of regulatory and market access challenges faced by certain technologies.
- It will help the development of proposals for guidance and common specifications in the field of medical devices

# Supporting Artificial Intelligence Innovations

- **AI regulatory sandboxes (Art. 57 (5) AI Act)**
  „a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market“
  (implementing Act to be adopted in 2025)
- **Digital Europe Program:**
  - **Establishment of sectoral Testing and Experimentation Facilities (TEFs)**
  - 4 established under the AI Act (Art. 84 AI Act)
  - **One for Health AI and Robotics (TEF Health)**
    technical and scientific support for Health AI providers and notified bodies

# Notified Body Increased Capacity NoBoCap Project

- EU4Health WP 2022
- **Supporting the development of the personnel of Notified Bodies** and third parties (deliverable: creation of a Job Board matchmaking plattform)
- **Capacity building of market operators**
  - training courses for NB staff / manufacturers
  - E-guided tool for manufacturers to help locate the most suitable Notified Body
  - Emerging Technology Identification form

# Innovative Health Initiative

- Public private partnership with a total budget of **2,4 billion EUR** jointly funded by the EU and industry associations, representing Europe's life science industries
- Aim is to translate health research and innovation into tangible benefits for patients and society
- In 2022: broadened scope now also including medical devices
- **New IHI project** to develop a harmonised framework and accompanying recommendations **for conducting early feasibility studies (EFS)** in the EU
  - Will enforce EU competitiveness
  - Ensure that EU patients gain access to innovative medical technologies

# Non-legislative measures

## ACTIONS TO INCREASE THE CAPACITY OF NOTIFIED BODIES AND HELPING PREPARE MANUFACTURERS

Position paper by Medical Device Coordination Group identifying actions to increase notified body capacity, the access to notified bodies and manufacturer preparedness (MDCG 2022-14 position paper)

**Increasing the number of notified bodies**

**Consortium** (NoBoCap) developing actions to increase the capacity of notified bodies and the preparedness of manufacturers (trainings) and facilitating access to notified bodies, **especially for SMEs** (matchmaking platform) (EU4Health)

Supporting coordination between **notified bodies** (EU4Health)

Tailored solutions for **orphan devices**

**Targeted support to SMEs** through Enterprise Europe Network

**NEW**: Development of further supporting tools such as **translation of nomenclatures**

## SUPPORT FOR INNOVATION AND ADDRESSING SPECIAL NEEDS

Pilot on **scientific advice by expert panels for clinical development strategies** for high-risk devices

**Orphan device support** programme, focussed on paediatrics (EU4Health)

**NEW**: Additional pilots with **expert panels to support conformity assessment**

## STOCK TAKING OF REGULATORY FRAMEWORK AND TRANSITION (EU4HEALTH)

Study on **governance and innovation**

Study to **monitor availability of medical devices on EU market**

**NEW**: Studies supporting the targeted evaluation of MDR/IVDR

## SUPPORT TO REGULATORY INFRASTRUCTURE AND PROCESSES (EU4HEALTH)

Support for **European database on medical devices**

Support for **designated EU reference laboratories** (*in vitro* diagnostics)

Joint Action on **market surveillance**

**NEW**: **Horizon scanning** for medical devices (EU4Health)

# Thank you!

*Contacts:*

European Commission - Directorate-General for Health and Food Safety (DG SANTE)
*Unit D.3 Medical Devices*
SANTE-MED-DEV@ec.europa.eu



European Commission

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# PANEL DISCUSSION
# THE ROAD TO MAKING THE EU THE LEADING AND INNOVATION FRIENDLY MEDICAL DEVICES/IVD/ DIGITAL HEALTH TECHNOLOGIES REGULATORY SYSTEM

**Mariana Madureira**
INFARMED
Senior Officer, Health Products Directorate

**Petra Zoellner**
MEDTECH EUROPE
Director Regulator Affairs

**Cristina Bescos**
EIT HEALTH
Director of Innovation / Chief Growth Officer

**Nathalie Seigneuret**
INNOVATIVE HEALTH INITIATIVE (IHI)
Senior Scientific Project Manager

Co-funded by the European Union

**WEDNESDAY**
**SEPTEMBER 25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# Your questions?

SLIDO.COM

Join Slido at

https://app.sli.do/event/7YbioqsA2WMWb14SeCfqPj

Co-funded by the European Union

WEDNESDAY
SEPTEMBER 25, 2024
Brussels

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

# MDCG NEW TECHNOLOGY WG

## PANEL DISCUSSION: THE ROAD TO MAKING THE EU THE LEADING AND INNOVATION FRIENDLY MEDICAL DEVICES/IVD/ DIGITAL HEALTH TECHNOLOGIES REGULATORY SYSTEM

Mariana Madureira

EU4Health NoBoCap 1st Summit, 25 September 2024

REPÚBLICA PORTUGUESA
SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

# MDCG NEW TECHNOLOGIES WG

1. Notified bodies oversight (NBO)
2. Standards
3. Clinical investigation and evaluation (CIE)
4. Post-market surveillance and vigilance (PMSV)
5. Market Surveillance (MS)
6. Borderline and classification (B&C)
7. New technologies
8. EUDAMED
9. Unique device identification (UDI)
10. International matters
11. In vitro diagnostic medical devices (IVD)
12. Nomenclature
13. “Annex XVI” products

## MDCG NT WG

**Chair:** Nada Alkhayat (EC)

**Co-chairs:**
Mariana Madureira (PT – INFARMED)
Robert Geertsma (NL - RIVM)

https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en#seven

# TERMS OF REFERENCE OF THE MDCG WORKING GROUP

## WORKING GROUP ON NEW TECHNOLOGIES

### 1. Tasks and roles

The Working Group on New Technologies provides assistance to the MDCG on issues related to application of new and emerging technologies to medical devices under Regulation (EU) 2017/745 (MDR) and *in-vitro* diagnostic medical device under Regulation (EU) 2017/746 (IVDR), including software, apps and cybersecurity. In particular, the group analyses the adequacy of the existing regulatory framework in relation to those issues and technologies and, where challenges are identified, it provides recommendations to the MDCG.

The group contributes to the development of proposals for guidance and common specifications in the field as referred to in Article 9 of MDR/Article 9 of the IVDR.

The group elaborates proposals for the review of Commission Regulation (EU) 207/2012 on electronic instructions of use of medical devices.

The group continuously performs screening of the available sources for identification of novel, emerging technologies which inherit medical/clinical potential.

https://health.ec.europa.eu/document/download/dbb9434c-a5ee-497b-be88-44e15ba314e2_en?filename=md_tor_wg7_nt_en.pdf

# MDCG NT WG

## PUBLICATIONS

# New technologies

| Reference | Title | Publication |
|---|---|---|
| MDCG 2023-4 | Medical Device Software (MDSW) – Hardware combinations Guidance on MDSW intended to work in combination with hardware or hardware components | October 2023 |
| Infographic | Is your **software** a Medical Device? | March 2021 |
| MDCG 2020-1 | Guidance on **clinical evaluation** (MDR) / **Performance evaluation** (IVDR) of medical device software | March 2020 |
| MDCG 2019-16 rev.1 | Guidance on **cybersecurity** for medical devices | December 2019 |
| MDCG 2019-11 | **Qualification and classification of software** - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 | October 2019 |

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec13

# MDCG NT WG

## CURRENT TOPICS

- **Interplay between AI Act and MDR/IVDR** (workshop held on 28/05/2024 based on the *"Feedback on NET WG 2022 FAQ on interplay between AIA.MDR-IVDR" + new questions proposed by NT WG)*

**WP 1**

- **Guidance on the Legal status of app providers** – interplay MDR/IVDR and Digital Services Act (DSA)
- **Targeted revision of MDCG 2019-11** "Qualification and classification of software" (e.g. integrating examples on MDSW intended to treat)
- **Electronic instructions for use** (the survey for healthcare professionals seeks feedback on potentially expanding the scope of eIFU Implementing Regulation (EU) 2021/2226 to include all professional-use medical devices – open until 11 October 2024)

**WP 4**

- **NET WG Horizon scanning System**



**WP 3**

# MDCG NT WG
## CURRENT TOPICS

IMDRF International Medical Device Regulators Forum

WP 5

### International cooperation

- **Software as a Medical Device WG**
  - **Medical Device Software: Considerations for Device and Risk Characterization** (consultation closed 02/05/2024)
- **Artificial Intelligence / Machine-Learning enabled WG**
  - **Good machine learning practice for medical device development - Guiding Principles** (consultation closed 30/08/2024)
- **Personalised Medical Devices WG** (drafting of training materials for the documents N49 – Definitions for personalised medical devices and N58 – PMD regulatory pathways)

### Additional activities

WP 6

- **Nanomaterials** (to assess Commission recommendation on new definition for nanomaterial)
- **Supporting innovation/Innovative medical devices** (including analysis of other regulators' approaches to innovative medical devices/ follow-up on IMDRF sessions on specialized regulatory pathways)

# OBRIGADA
# THANK YOU


NoBoCap COMMUNITY

QUALIFY TO CERTIFY

SUMMIT BY NOBOCAP COMMUNITY
UNLOCKING THE MDR/IVDR REGULATION FOR INNOVATORS IN EUROPE

REPÚBLICA PORTUGUESA
SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap
COMMUNITY

QUALIFY TO CERTIFY

# COFFEE BREAK
# 14:45–15:00

Co-funded by
the European Union

**WEDNESDAY**
**SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# CHANGE IN TODAYS REALITY FOSTERED BY THE NOBOCAP COMMUNITY: INNOVATION HUBS AND NOTIFIED BODIES INVOLVED IN NOBOCAP COMMUNITY AS KEY ENABLERS TO BUILD OUT AN INNOVATION SUPPORTIVE REGULATORY SYSTEM

15:00–16:15

**WEDNESDAY**
**SEPTEMBER 25, 2024**

Brussels

#NOBOCAPSUMMIT2024

Co-funded by the European Union

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# PANEL DISCUSSION
# CHANGE IN TODAYS REALITY FOSTERED BY THE NOBOCAP COMMUNITY: INNOVATION HUBS AND NOTIFIED BODIES INVOLVED IN NOBOCAP COMMUNITY AS KEY ENABLERS TO BUILD OUT AN INNOVATION SUPPORTIVE REGULATORY SYSTEM


**Richard Holborow**
NB - BSI
Global Head of Clinical Compliance

**Geofrey De Visscher**
NB- SGS
Head of Notified Body



Co-funded by the European Union


**WEDNESDAY**
**SEPTEMBER 25, 2024**
Brussels

NoBoCap COMMUNITY

QUALIFY TO CERTIFY

# Your questions?

SLIDO.COM

Join Slido at

https://app.sli.do/event/7YbioqsA2WMWb14SeCfqPj

Co-funded by the European Union

WEDNESDAY
SEPTEMBER 25, 2024
Brussels

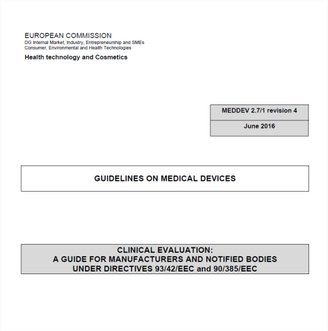
NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

# Certificates with Conditions

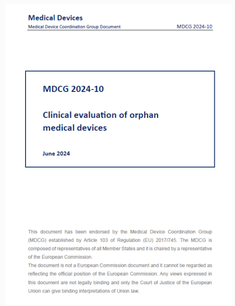
Consideration from A Notified Body.



EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Health technology and Cosmetics

MEDDEV 2.7/1 revision 4
June 2016

GUIDELINES ON MEDICAL DEVICES

CLINICAL EVALUATION:
A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
UNDER DIRECTIVES 93/42/EEC and 90/385/EEC


Medical Devices
Medical Device Coordination Group Document MDCG 2024-10

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.
The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.


4.8. Decisions and Certifications

The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to:

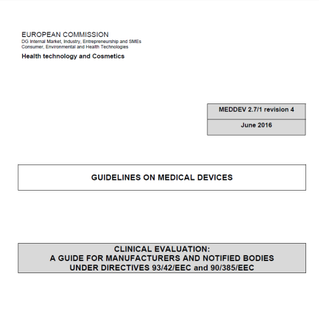
— decide, based on the assessment documentation and additional information available, whether the requirements of this Regulation are fulfilled,

— decide, based on the results of its assessment of the clinical evaluation and risk management, whether the post-market surveillance plan, including the PMCF plan, is adequate,

— decide on specific milestones for further review by the notified body of the up to date clinical evaluation,

— decide whether specific conditions or provisions need to be defined for the certification,

*Annex VII Section 4.8 EU MDR 2017/745 - EU IVDR 2017/746 has a similar provision.*

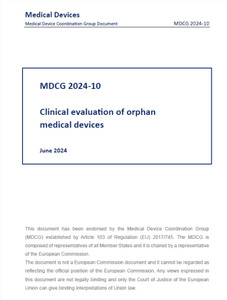


EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Health technology and Cosmetics

MEDDEV 2.7/1 revision 4
June 2016

GUIDELINES ON MEDICAL DEVICES

CLINICAL EVALUATION:
A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
UNDER DIRECTIVES 93/42/EEC and 90/385/EEC



Medical Devices
Medical Device Coordination Group Document MDCG 2024-10

MDCG 2024-10

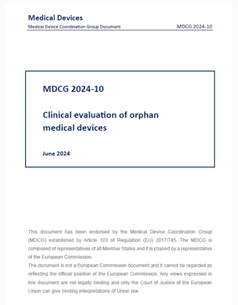
Clinical evaluation of orphan medical devices

June 2024

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.
The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.



Certificates with conditions provide opportunity for Notified Bodies to issue certificates where there maybe challenges in obtaining data in the pre-market stage and/or when closer surveillance is required.



Medical Devices
Medical Device Coordination Group Document MDCG 2024-10

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.
The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.



EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Health technology and Cosmetics

MEDDEV 2.7/1 revision 4
June 2016

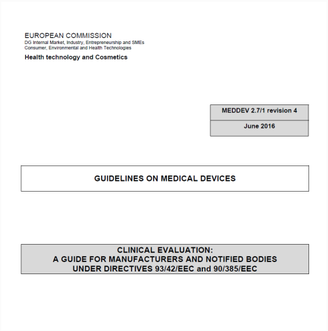
GUIDELINES ON MEDICAL DEVICES

CLINICAL EVALUATIO
A GUIDE FOR MANUFACTURERS AND
UNDER DIRECTIVES 93/42/EEC ar

CORE-MD
Coordinating Research and Evidence for Medical Devices

Report on conditions on certificates by Notified bodies

- Certificates with conditions is not a new concept but never had a regulatory requirement within the directives like we see in the regulations.
- The recent CORE-MD research programme identified notified bodies used certificates with conditions less than <1% under the directives.
- Experience suggests they were issued for novel devices for controlled market release with limited preliminary clinical data.



EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Health technology and Cosmetics

MEDDEV 2.7/1 revision 4
June 2016

GUIDELINES ON MEDICAL DEVICES

CLINICAL EVALUATION:
A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
UNDER DIRECTIVES 93/42/EEC and 90/385/EEC



European Commission

Medical Devices
Medical Device Coordination Group Document MDCG 2022-14

MDCG 2022-14

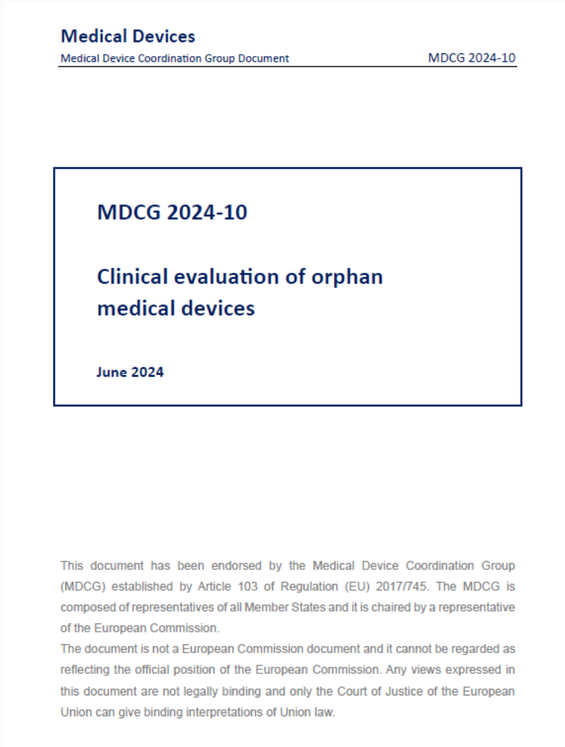
MDCG Position Paper

Transition to the MDR and IVDR

Notified body capacity and availability of medical devices and IVDs

August 2022

- MDCG 2022-14 calls on the notified bodies to make better use of conditions of certificates to support the implementation of the MDR and IVDR.
- MDCG 2024-10 discusses the limitations of data collection for orphan devices.
- MDCG 2024-10 recommends that certificates with conditions should be used for orphan devices to ensure that post market data collection focuses on collecting clinical data to confirm safety and performance.

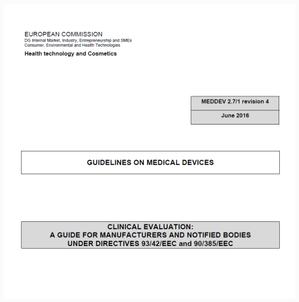

Medical Devices
Medical Device Coordination Group Document MDCG 2024-10

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

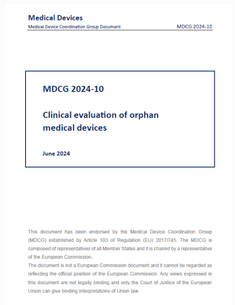
This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.
The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.



EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Health technology and Cosmetics

MEDDEV 2.7/1 revision 4
June 2016

GUIDELINES ON MEDICAL DEVICES

CLINICAL EVALUATION:
A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
UNDER DIRECTIVES 93/42/EEC and 90/385/EEC


Medical Devices
Medical Device Coordination Group Document MDCG 2024-10

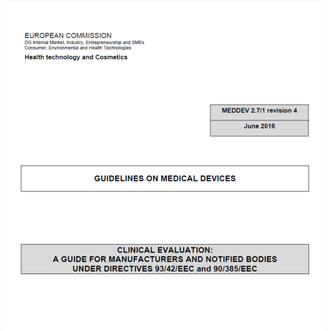
MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.
The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

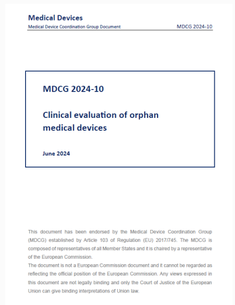

- Certificates with conditions can be a great method to support innovation and novelty.
- There are often limitations in preliminary clinical data associated with truly innovative and novel devices.
- A devices safety and performance is really established when the device is placed in the ‘real world’ .
- Such conditions include reporting back to notified bodies at a frequent interval through PMCF reports.



EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Health technology and Cosmetics

MEDDEV 2.7/1 revision 4
June 2016

GUIDELINES ON MEDICAL DEVICES

CLINICAL EVALUATION:
A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
UNDER DIRECTIVES 93/42/EEC and 90/385/EEC


Medical Devices
Medical Device Coordination Group Document MDCG 2024-10

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.
The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.


- Certificates with conditions can be advantageous to encourage a thriving regulatory and innovative environment.

- Certificates with conditions are not opportunities to plug gaps where there have been opportunities to have gathered clinical data.

NoBoCap
COMMUNITY


Co-funded by
the European Union

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

NoBoCap
COMMUNITY

# LOOKING FORWARD TO SEEING YOU IN 2025!

## New Edition Coming 14-15 October 2025

**TUESDAY & WEDNESDAY**
**SEPTEMBER 24-25, 2024**
Brussels

**#NOBOCAPSUMMIT2024**

QUALIFY TO CERTIFY