MedTech Europe
from diagnosis to cure

European Regulations on Medical Technologies

MedTech Europe's Perspective

14 October 2024

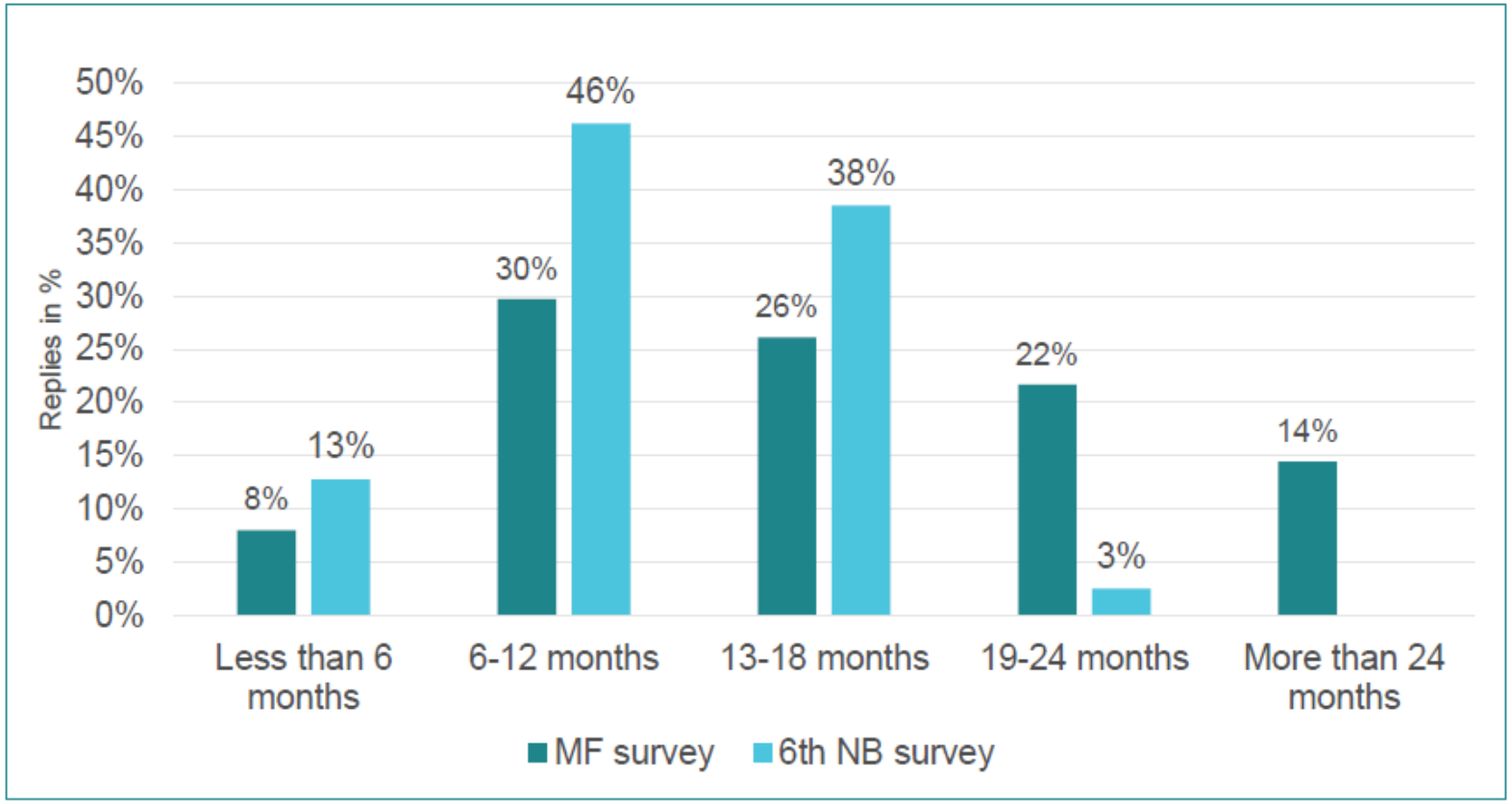
MDCG-Stakeholder meeting, Brussels

[redacted], *Senior Manager Regulatory Affairs, MedTech Europe*

Timelines

An example: EU QMS certification under MDR

GÖG survey



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

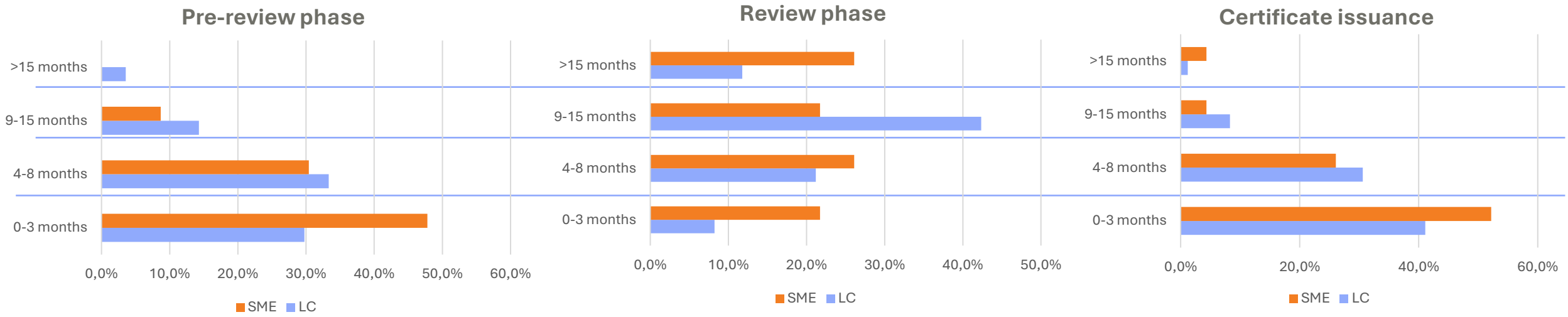
Significant difference between the data reported by manufacturers and reported by Notified Bodies

Timelines

EU QMS certification under MDR

(Total responses: 88)

MedTech Europe survey



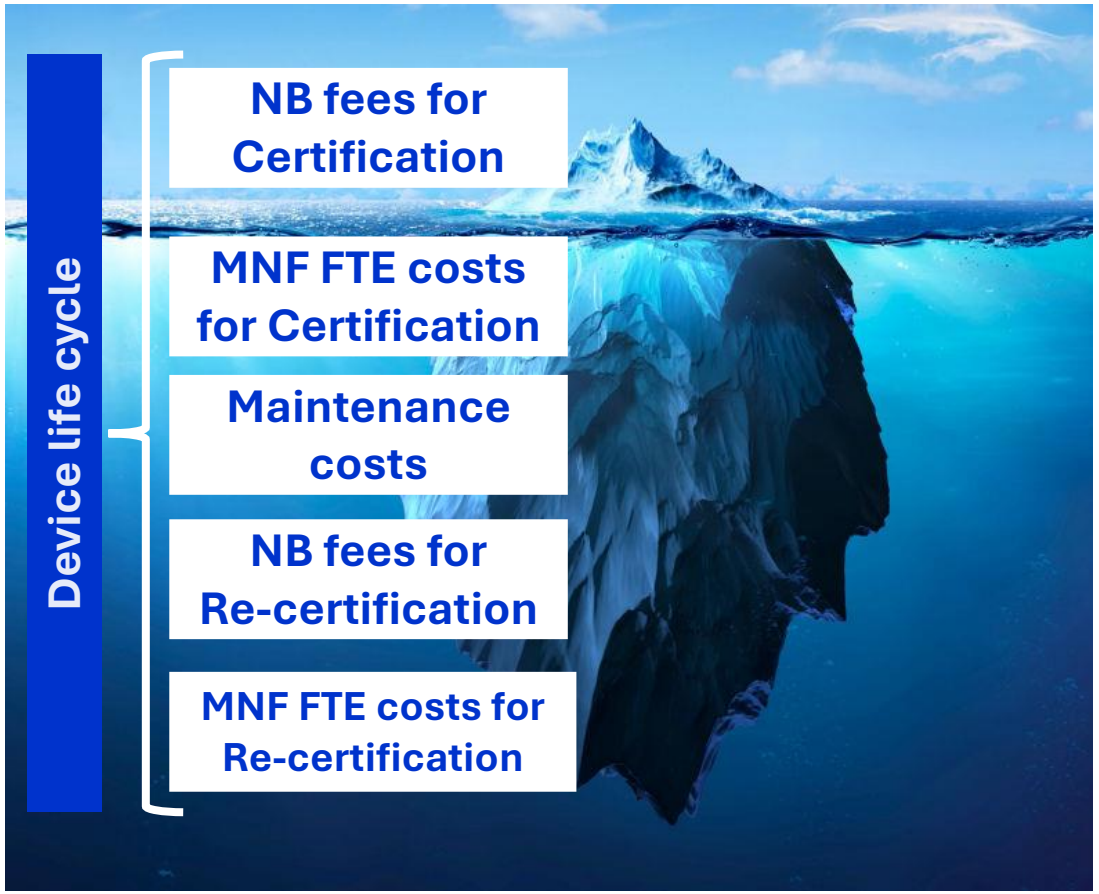
- EU QMS certification: average completion time **~19.5 months**
- **Little difference** between SMEs and large companies regarding timelines.

Phase	Percentage of total time
Pre-Review	**28%**
Review	49%
Issuance	**23%**

51%

Regulatory Costs to obtain & maintain IVDR/MDR certification throughout the device life-cycle

MedTech Europe survey



- **NB fees for certification increased ~100% for QMS & for TD assessment certification**.
  - Delays and time needed for certification are significant contributors
- **Many additional costs need to be accounted for apart from NB certification fees,** including:
  - Manufacturer's FTE costs to complete certification
  - Maintenance costs that are needed to maintain the certificates (e.g. the fees for PMS reports, vigilance and annual NB surveillance)
  - Manufacturer's FTE costs to maintain certification
  - NB fees for re-certification after the 5-years period

Regulatory Costs: Overview of *average* costs to obtain & maintain MDR certification throughout device life-cycle

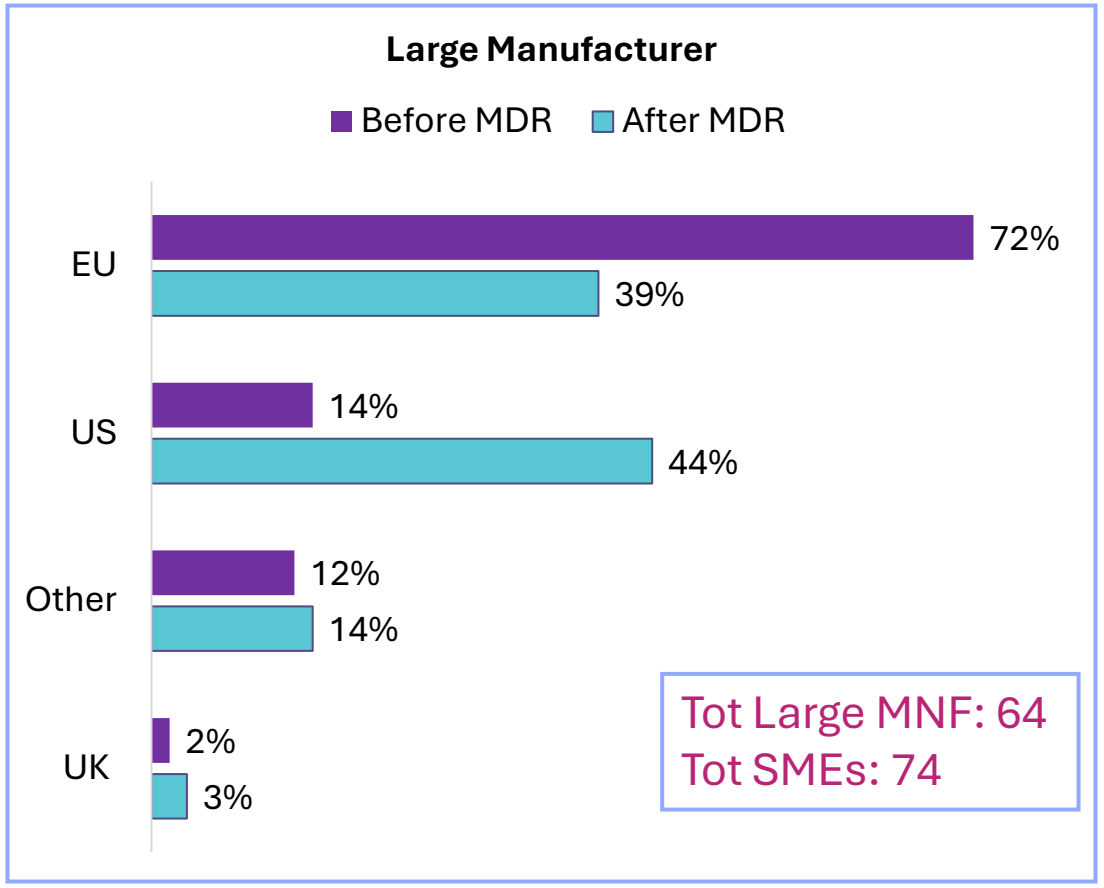
MedTech Europe survey

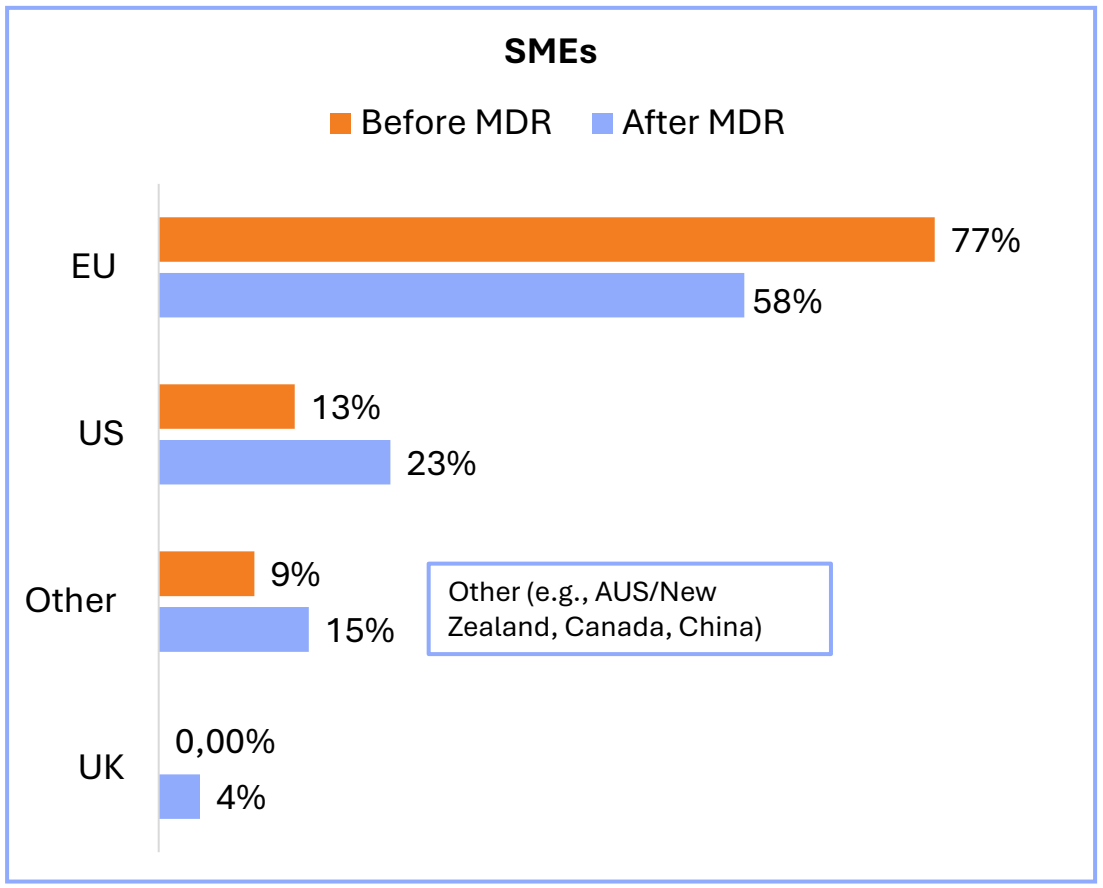
	QMS	Technical documentation assessment
Certification	NB fees for cert. ~**136,981 €** Manufacturer's FTE costs ~**490,525 €**	NB costs for cert. ~**176,202 €** Manufacturer's FTE costs ~**3,445,738 €**
Maintenance	Yearly maintenance costs for ALL classes subject to NB cert. ~ **99,648 €** Maintenance costs accumulated after 5-years ~ **498,242 €**	
Re-certification	**Limited data** at the present time – MedTech Europe ongoing efforts to gather more data	

Note: large variability in figures

Innovation Launch: Preferred geography before and after MDR Date of Application

MedTech Europe survey





MDR dramatically affects the choice of the EU as the main option for a first regulatory approval by large manufacturers and SMEs, with a **reduction of 33% and 19% respectively**.
On the contrary, the choice of **other geographies increased significantly**, especially the **US.**

EU industry welcomes and supports the Targeted Evaluation
A full legal proposal could take years…
We need different actions in the short-term

Urgent bridging measures with 'legal weight'

1. **Bring predictability** to **timelines & costs** in technical documentation assessment and change control
2. **Introduce accelerated pathway** for breakthrough **innovation**
3. **Adapt certification** to follow a life-cycle approach (**renewals**)

Support fixes of regulatory system through guidance and other tools

1. **Deliver on the goals of MDCG 2022-14** (structured dialogue, leveraging evidence, reduce tech doc. sampling burden…)
2. **Enabling electronic Instructions for Use (e-IFU)** for all medical technologies
3. **Promote global convergence** of regulations, specifically via Medical Device Single Audit Program (**MDSAP**) initiative

We continue to propose a **multistakeholder consortium**, including Competent Authorities, the European Commission, and notified bodies, to regularly address present and future challenges collaboratively

Additionally, a **package of legislative reforms** with input from the Targeted Evaluation

- Dramatically **enhance efficiency** and robustly increase Europe's **attractiveness for innovation** in medical technologies
- To underpin the above, **a single, dedicated governance structure** should be established which oversees and manages the regulatory system

MedTech Europe's Vision for the Future of our Regulatory System (see paper)

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Thank you

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