Lübecker Summer Academy 2021

The New Regulatory Framework for Medical Devices – An Industry Perspective

Dr. Christina Ziegenberg
stellv. Geschäftsführerin BVMed, Leitung Referat Regulatory Affairs & Recht
Bundesverband Medizintechnologie e.V.

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BVMed –
The German Medical Technology Association

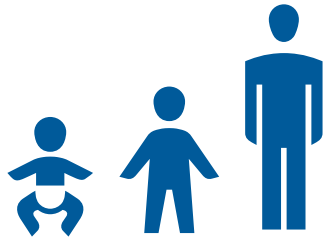
BVMed is an industry association that represents more than 230 industry, trade and supplier companies. Among the members of the association are 20 of the largest medical device manufacturers worldwide in the durables and consumer goods sector.

As a trade association, BVMed ***promotes and represents the combined interests of the medical technology industry and trade companies***. In various working groups, sectoral interest groups, focus and project groups, the association offers its members a platform for a constructive dialog and exchange of views.

BVMed ***represents the concerns of its member companies to policy makers and the public in general***. Not only is this achieved by information and public relations work, but also by participation in the development of laws, guidelines, and standards.

The experts of BVMed offer ***advice and training for the member companies*** with regard to all aspects of development, market access and the remuneration of medical devices, homecare services, or digital health applications.

Vision / Approach



BVMed is engaged in

> the optimal supply of the population with **high-quality medical devices**

and thus

> for the improvement of people's health and quality of life in all stages of life.

How to join? www.bvmed.de/mitglied-werden

#MDReady | The MDR takes shape

Truth is a sister of time.

05.05.2017 Publication MDR
25.05.2017 Entry into force MDR

~~26.05.2020 Start of validity of MDR old (DoA)~~

26.05.2021 Start of validity of MDR new (DoA)*

27.05.2024 End of the transition period (Grace Period)

27.05.2025 End of the sales period

03.05.2019 1st Corrigendum, Abl. L 117 p. 9
27.12.2019 2nd Corrigendum, Abl. L334, p. 165

2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025

26.05.2017 – 25.05.2021
Certificates according to MDD/AIMDD will continue to be issued

25.05.2021 – 26.05.2024
Certificates issued according to MDD/AIMDD are still valid for up to three years

2024 - 2025
Sale of MDD/AIMDD products

from 26.05.2017
MDR compliant medical devices can be placed on the market according to MDR

Date of Application; Regulation EU 2020/561 of the European Parliament and of the Council of 23 April 2020.

#MDReady | Regulatory Major Construction Site MDR

The set of rules is not yet fit for practice.

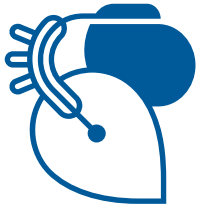
Notified Bodies:
Number and capacities
still too low

(AI)MDD devices:
Clinical data
partly difficult to collect

Innovations:
On hold and
probably shift outside the EU?

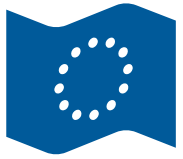
Grace Period:
Transfer of 20,000 certificates
by 2024 time-sensitive

Remote Audits:
No legal basis available
and not harmonized



Orphan Devices:
Lack of exception procedures

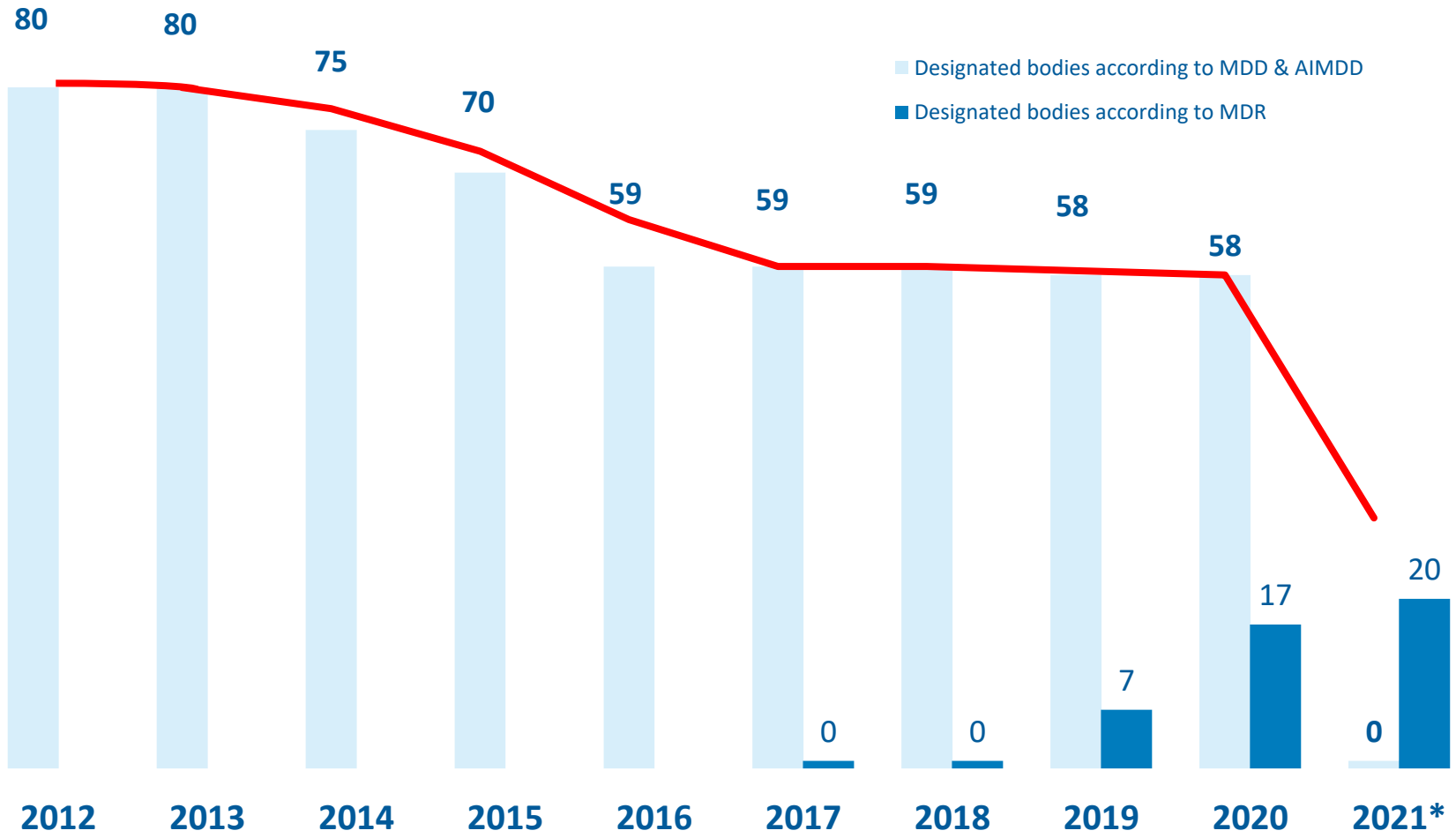
MDCG Guidelines:
Inconsistent and
without transition periods



EUDAMED:
Lack of functionality and
many open questions

#MDReady | Decrease of Notified Bodies

Notification process in Europe takes too long. Bottlenecks are foreseeable.



MDD Medical Device Directive (RL 93/42/EWG)

AIMDD Active Implantable Medical Devices (RL 90/385/EWG)

MDR Regulation on medical devices (EU) 2017/745

* From 26.05.2021 on

#MDReady | Decrease of Notified Bodies

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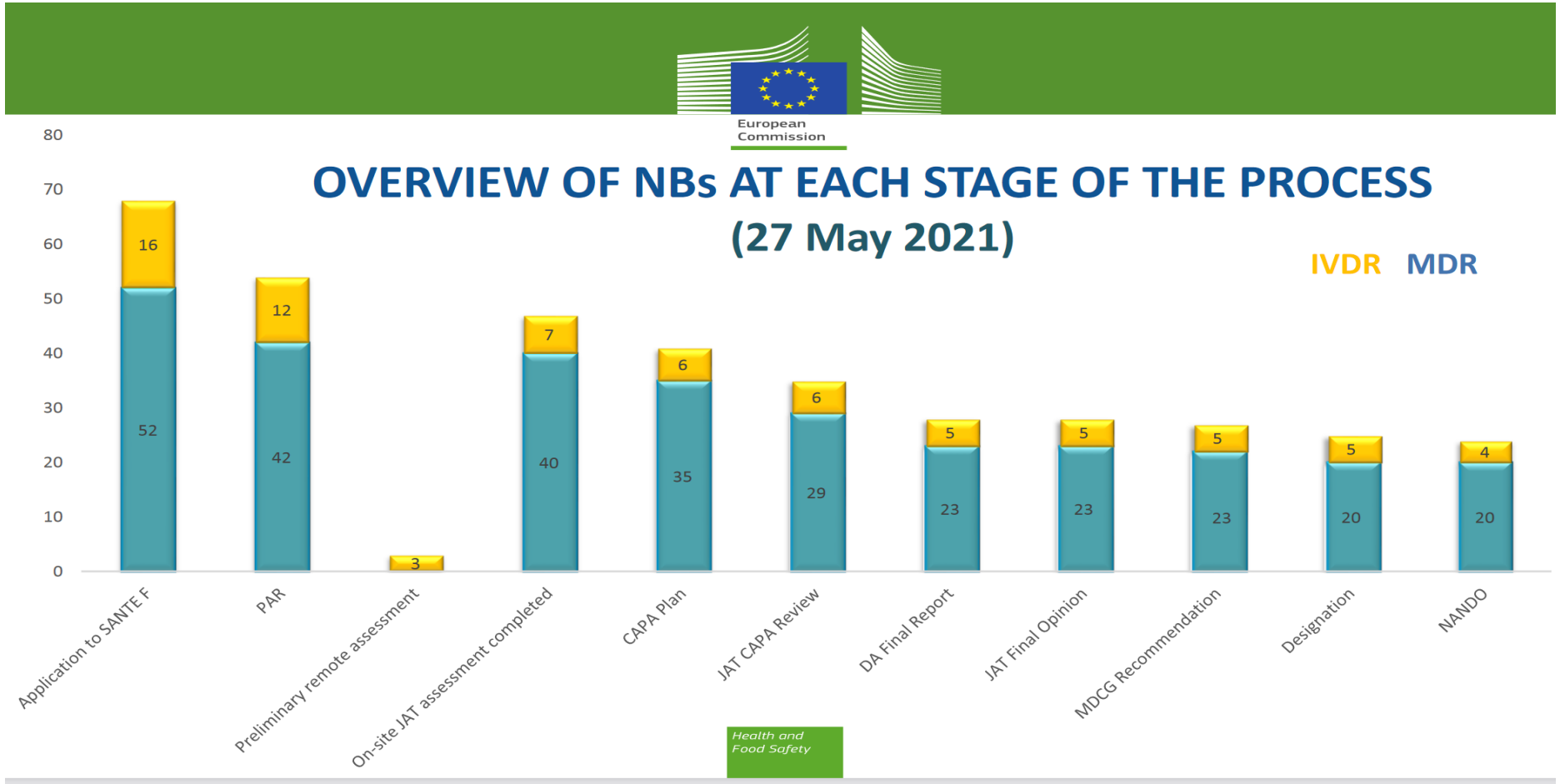
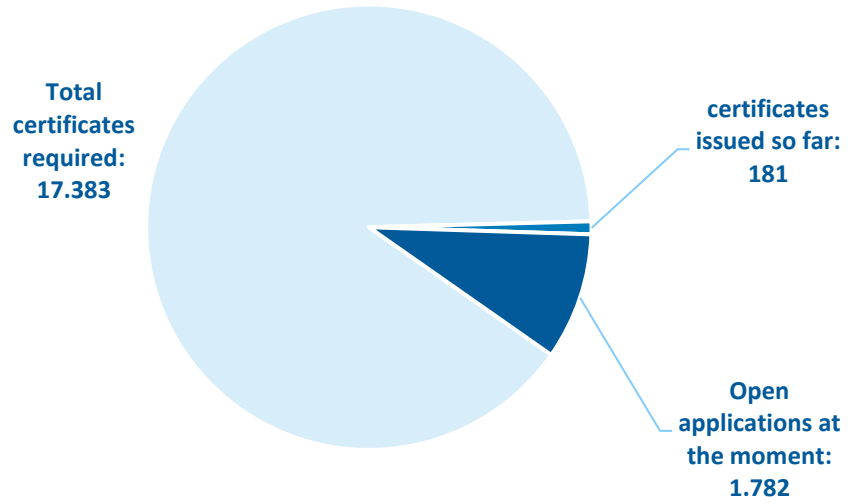
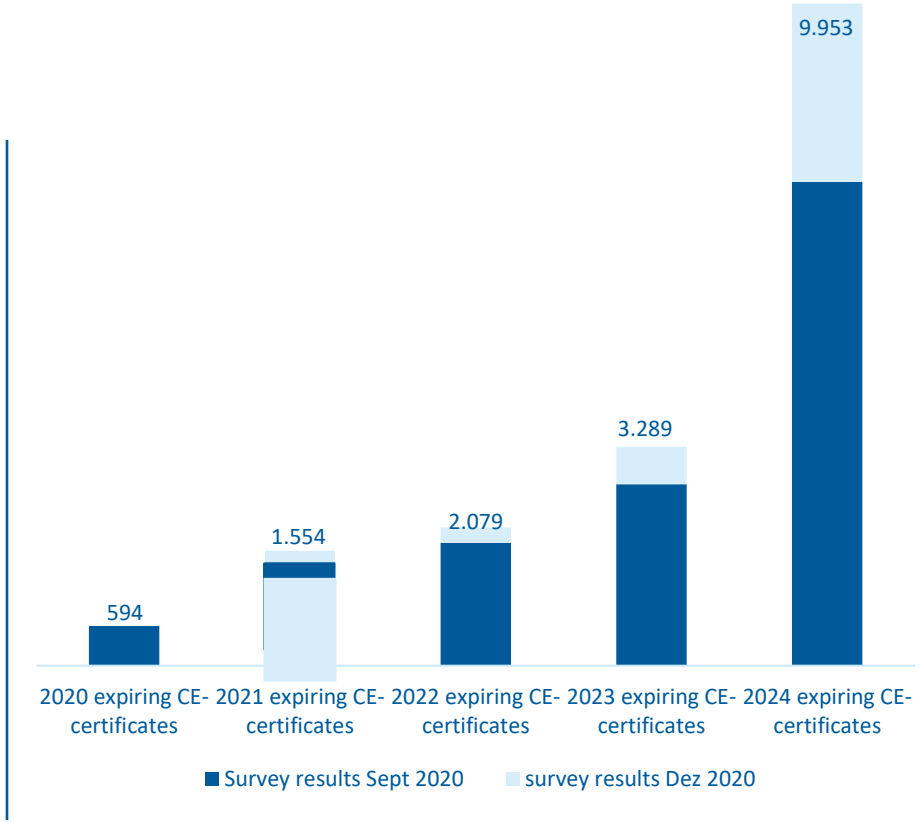


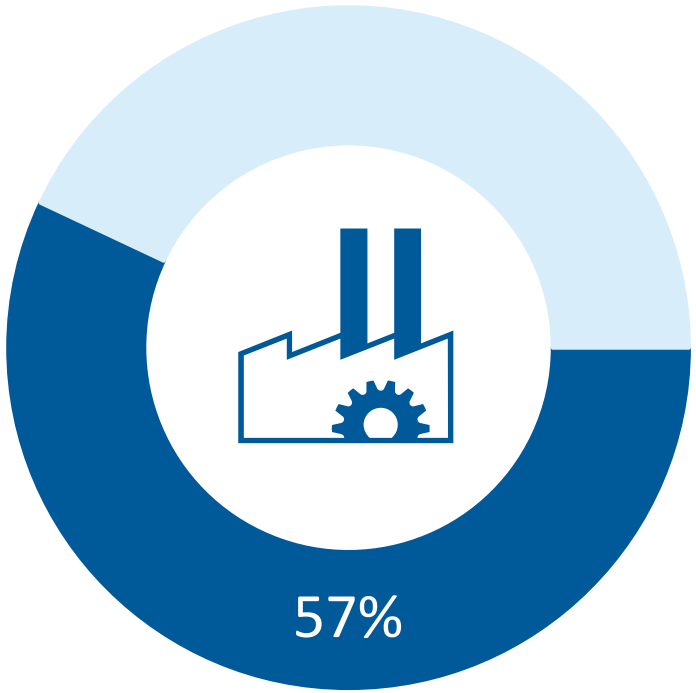
#MDReady | Bottleneck Grace Period MDR

The current resources of NB will not be sufficient to transfer all existing medical device certificates into the MDR. Bottlenecks are foreseeable.



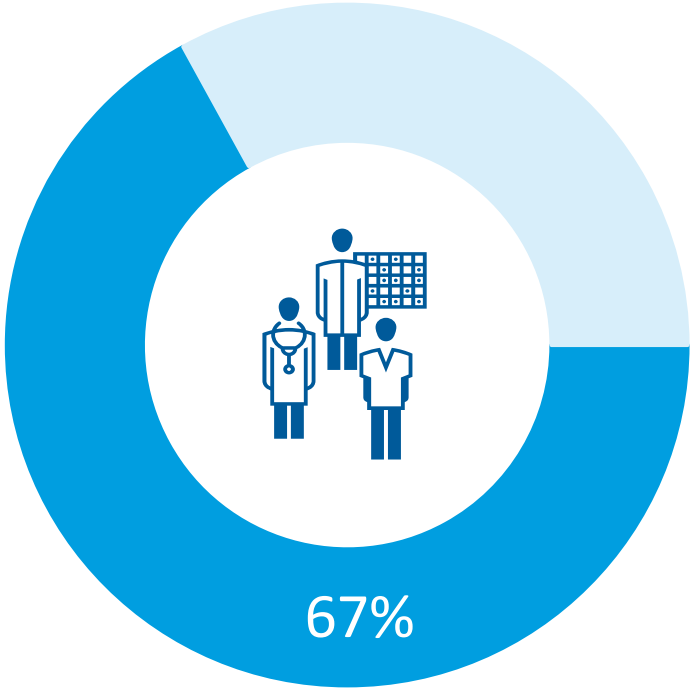


SME shapes the MedTech-sector



GROSS VALUE ADDED

More than half of MedTech's value creation is generated in SMEs

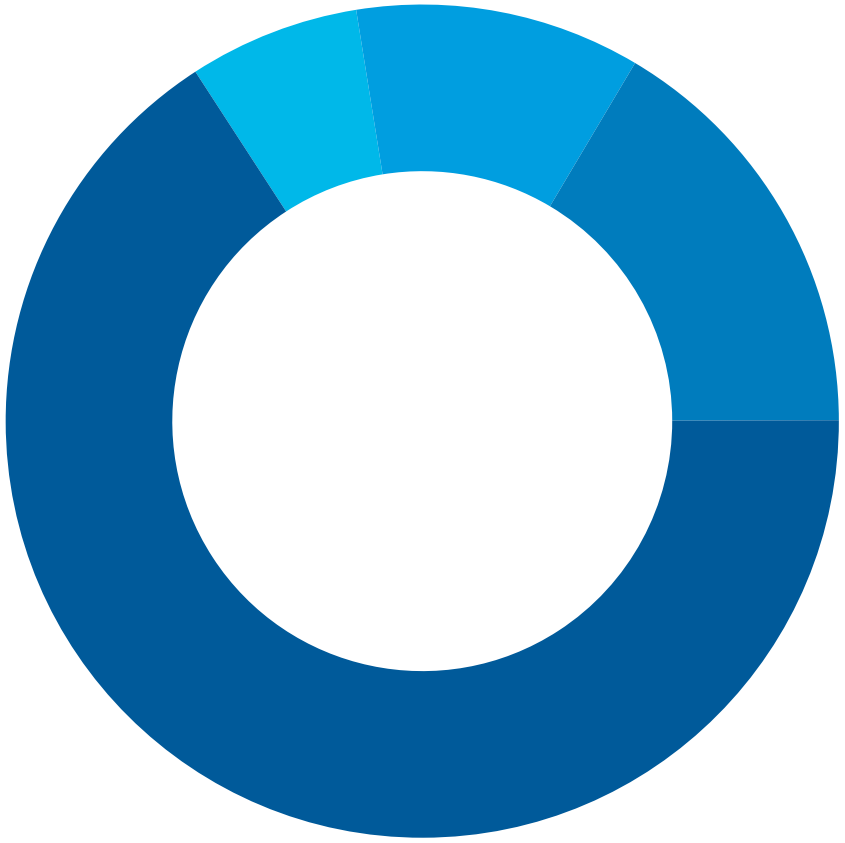


EMPLOYEES

SMEs are the employer for two-thirds of the medtech workforce

93 percent of MedTech-companies are SMEs

Number of MedTech companies in 2019 by employees



- >250 : 94 companies
- 100 - 249 : 157 companies
- 50 - 99 : 233 companies
- <20 - 50 : 934 companies

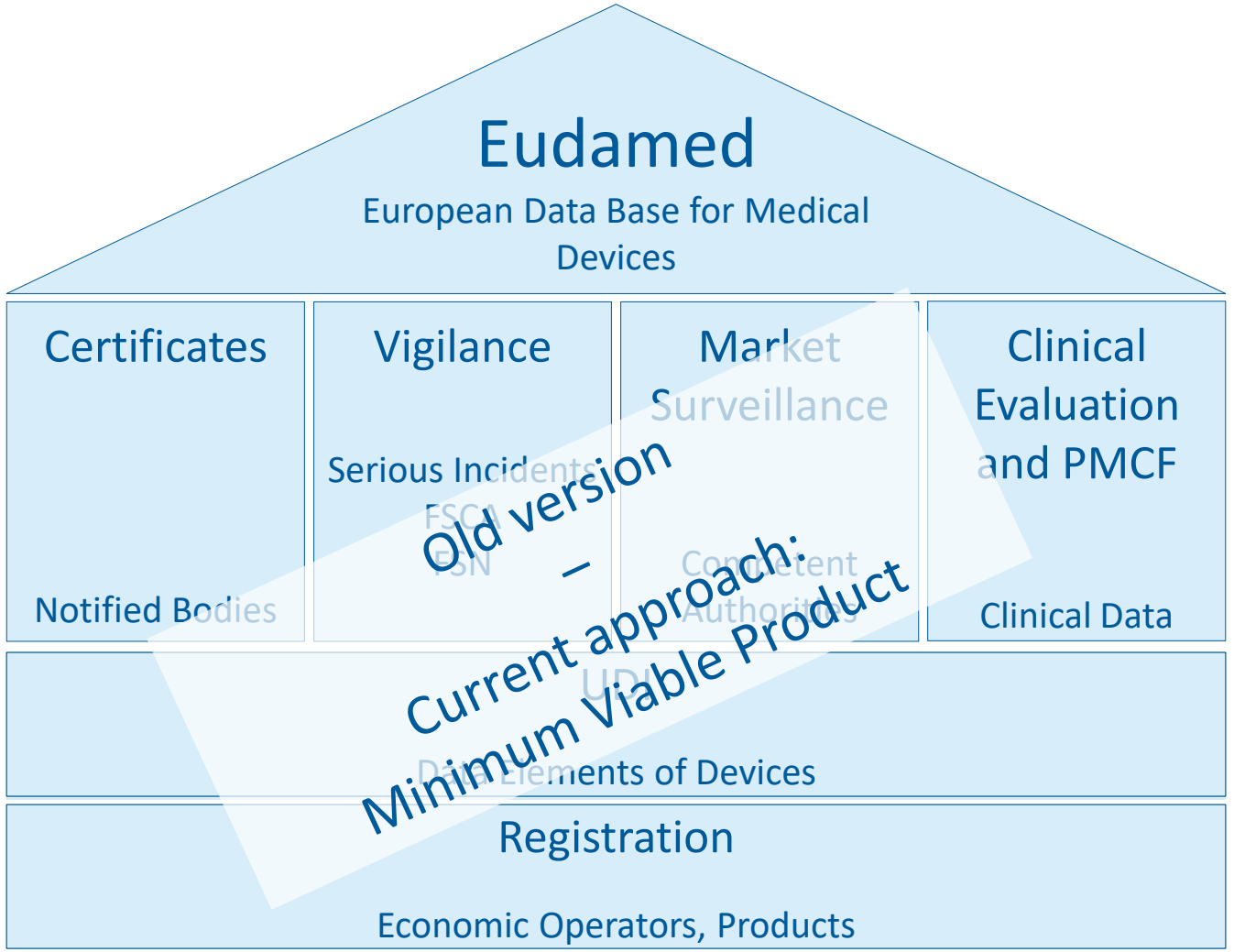
plus 13.000 Micro-enterprises

Harmonised Standards under the MDR

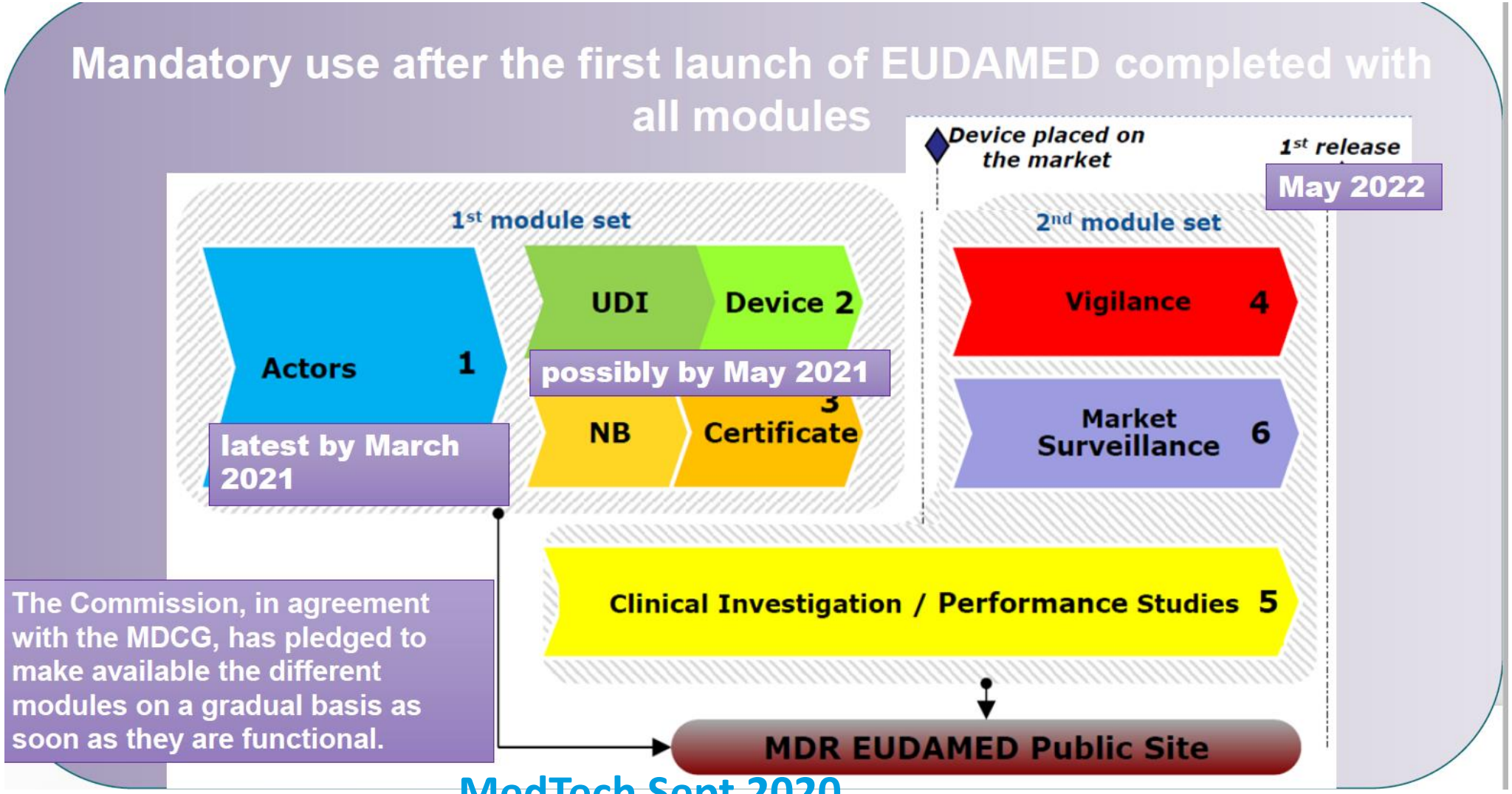
Lack of Harmonized Standards may compromise Patient Safety, will make Medical Devices more expensive and harm the competetiveness of European Industry.

- **Rejection of important Standards due to „Lack of Compliance“ via HAS Consultants by the COM**
- **Rejection of the COM Implementing Decision M/565 in mid 2020 by CEN/CENELEG.**
- **NEW HOPE – Harmonisation of Standards to MDR:**

  EU COM Implementing Decision M/575, 14.04.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

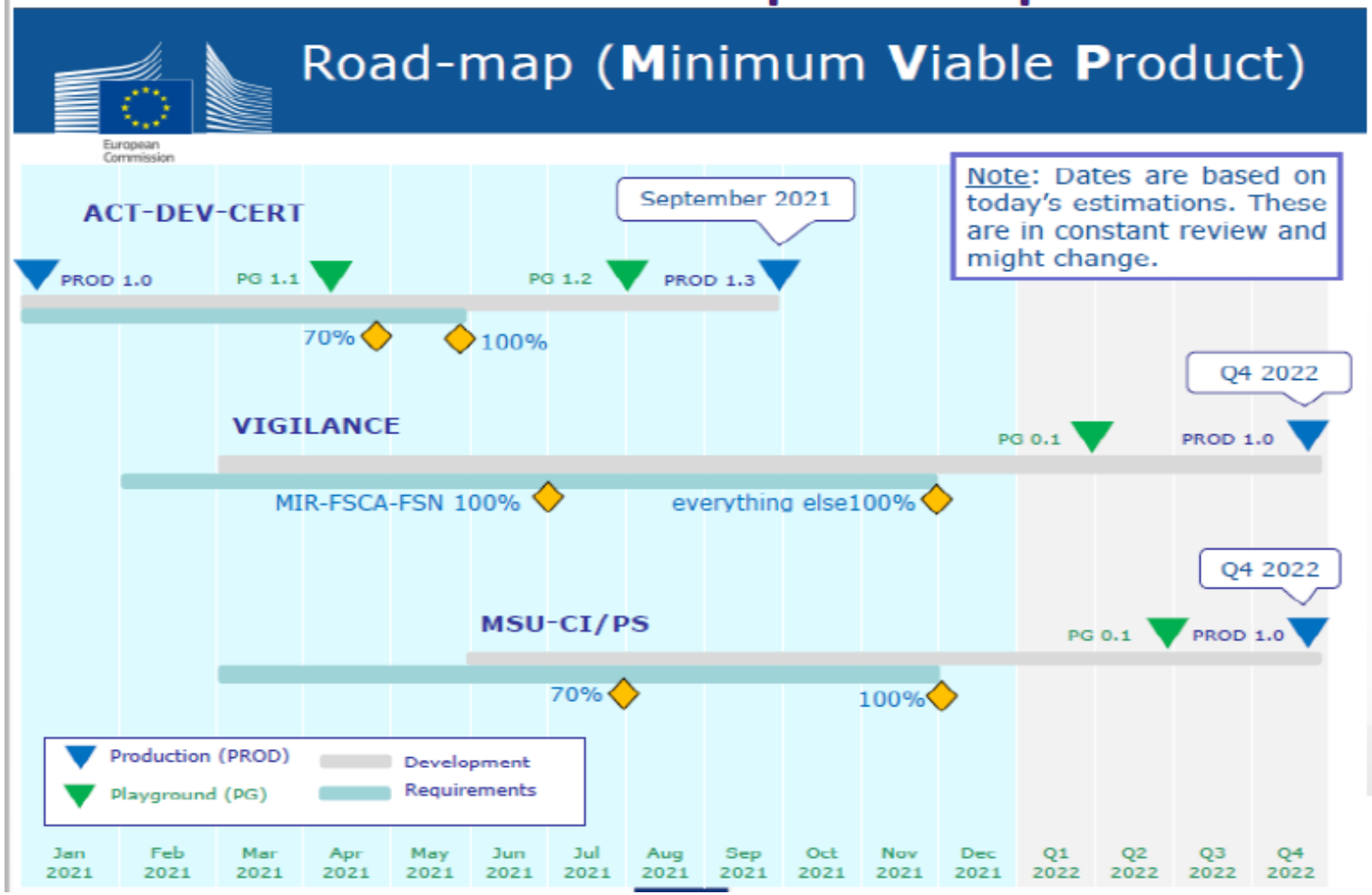


*https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en



MedTech Sept 2020

EUDAMED Roadmap – 27 Apr 2021



Target date to deliver all modules has changed!

May 2022 => Q4 2022

When will a fully functional EUDAMED = 'Minimum Viable Product' be launched?

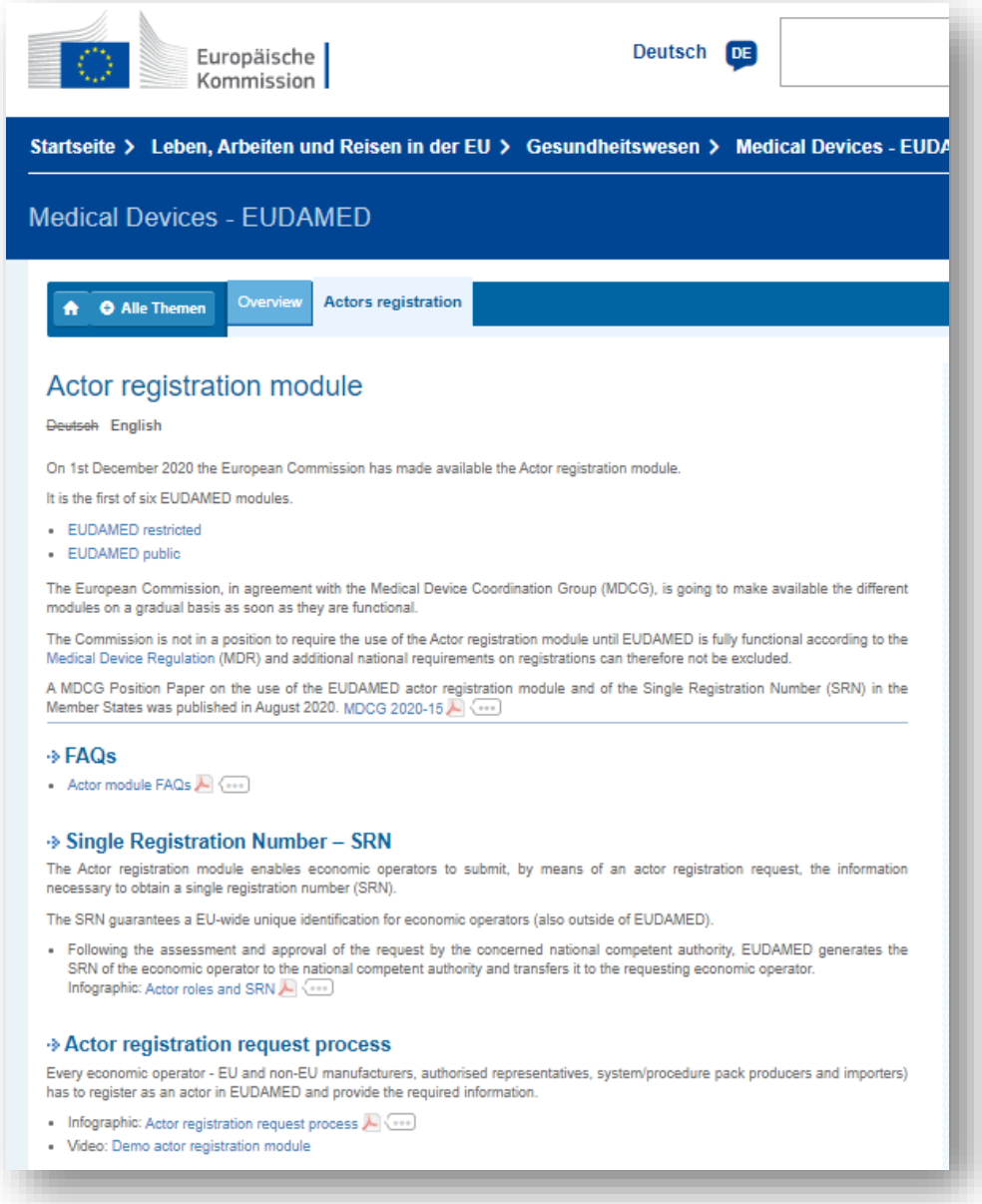
When is the audit scheduled to validate?

How long will it take?

When will the notice be published in the official journal?

MedTech Europe
from diagnosis to cure

EUDAMED



Europäische Kommission

Deutsch DE

Startseite > Leben, Arbeiten und Reisen in der EU > Gesundheitswesen > Medical Devices - EUDA

Medical Devices - EUDAMED

Alle Themen | Overview | Actors registration

Actor registration module

~~Deutsch~~ English

On 1st December 2020 the European Commission has made available the Actor registration module.

It is the first of six EUDAMED modules.

- EUDAMED restricted
- EUDAMED public

The European Commission, in agreement with the Medical Device Coordination Group (MDCG), is going to make available the different modules on a gradual basis as soon as they are functional.

The Commission is not in a position to require the use of the Actor registration module until EUDAMED is fully functional according to the Medical Device Regulation (MDR) and additional national requirements on registrations can therefore not be excluded.

A MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States was published in August 2020. MDCG 2020-15

FAQs

- Actor module FAQs

Single Registration Number – SRN

The Actor registration module enables economic operators to submit, by means of an actor registration request, the information necessary to obtain a single registration number (SRN).

The SRN guarantees a EU-wide unique identification for economic operators (also outside of EUDAMED).

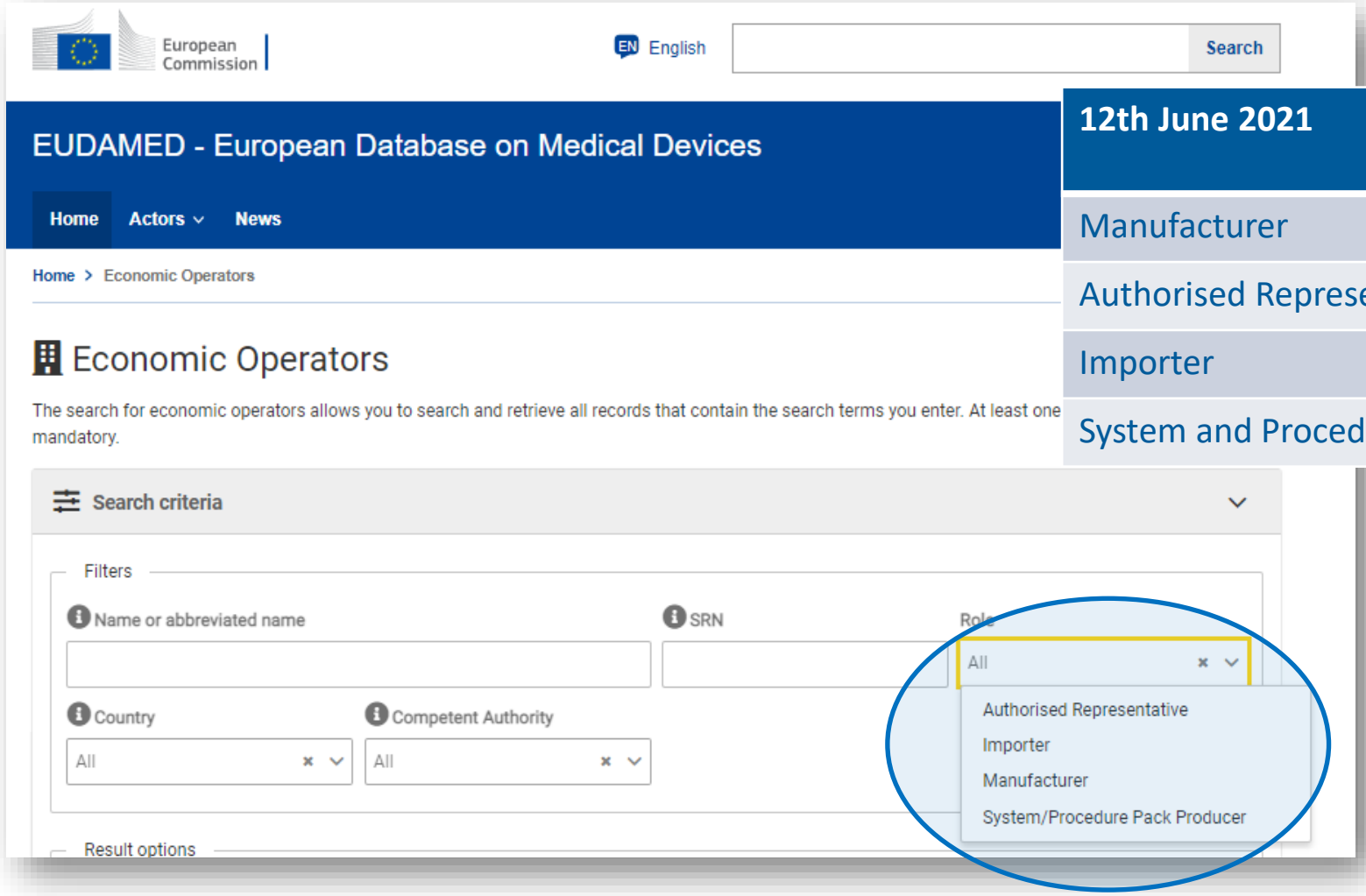
- Following the assessment and approval of the request by the concerned national competent authority, EUDAMED generates the SRN of the economic operator to the national competent authority and transfers it to the requesting economic operator.
  Infographic: Actor roles and SRN

Actor registration request process

Every economic operator - EU and non-EU manufacturers, authorised representatives, system/procedure pack producers and importers) has to register as an actor in EUDAMED and provide the required information.

- Infographic: Actor registration request process
- Video: Demo actor registration module

EUDAMED



12th June 2021	Euopean Union	Germany
Manufacturer	4143	1031
Authorised Representative	623	176
Importer	1485	215
System and Procedure Pack Producer	143	23

Bundesanzeiger 28.5.21 – Anouncement of BMG 26.05.2021: EUDAMED, SRN etc.

	Single Registration Number (SRN)	Regulatorischer Status des Produkts		
		Richtlinien konformes Produkt (AI)MDD	Produkte der Übergangsperiode (Art. 120.3 MDR) Legacy Device	MDR-Produkt
Wirtschaftsakteur	Hersteller	NEIN Nicht über die MDR geregelt. Werden seit dem 26. Mai 2021 nicht mehr auf den Markt gebracht.	JA MDR Art. 120.3	JA MDR Art. 10/11 inkl. Hersteller und Bevollmächtigte für Produkte gemäß MDR Art. 16.1, 17.2, 22.4, 23.2
	Bevollmächtigter			
	Importeur			JA gemäß MDR Art. 31.1
	Hersteller von Sonderanfertigungen			NEIN ausgeschlossen gemäß MDR Art. 31.1
	Hersteller von Systemen und Behandlungseinheiten			NEIN Nicht gefordert gemäß MDR Art. 31.1
	Händler	NEIN Nicht gefordert gemäß MDR Art. 31.1		

#MDReady | Overview of regulations

Highly complex. Welcome to the jungle!

CURRENT
until May 25, 2021

MDD / AIMDD
23/17 Articles
12/8 Annexes
65/39 pages

→

MPG
44 Paragraphs
19 pages

+

Regulations
MPV
MPSV
MPKPV
DIMDIV*
MPGebV

NEW
from May 26, 2021 on

Regulation (EU) 2017/745 MDR
123 Articles
17 Annexes
175 pages

+

MPEUAnpG (Article Act)

MPDG
99 Paragraphs
33 pages

+

MPEUAnpV

+ Implementing acts
+ Delegated acts

Legally non-binding, but recommended
+ harmonized standards
+ MDCG Guidelines

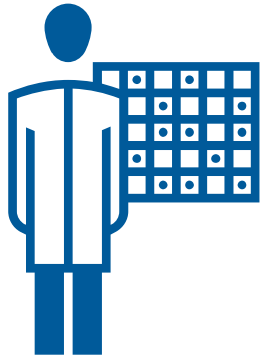
modified
- MPBetreibV
- **MPAV**
- APBetrV
- MeMBV

new
- MPAMIV
- MPDG Fees Regulation**

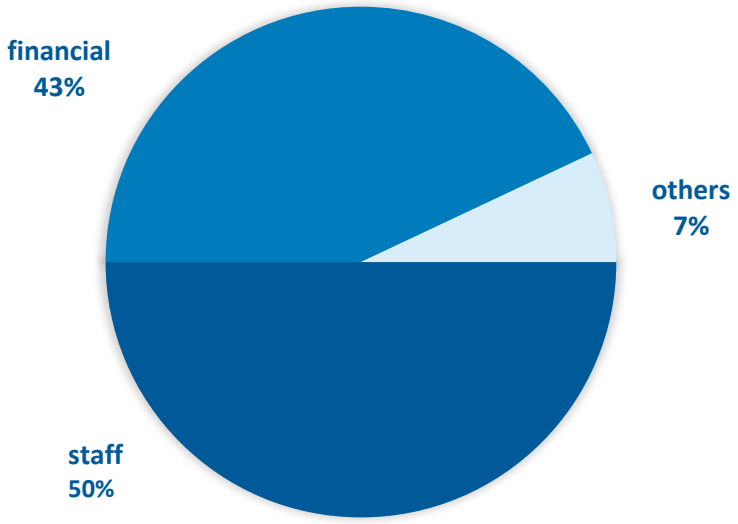
* Repealed on May 26, 2020
** will be transferred into another regulation on October 1, 2021

#MDReady | (Im)mediate additional costs of the MDR

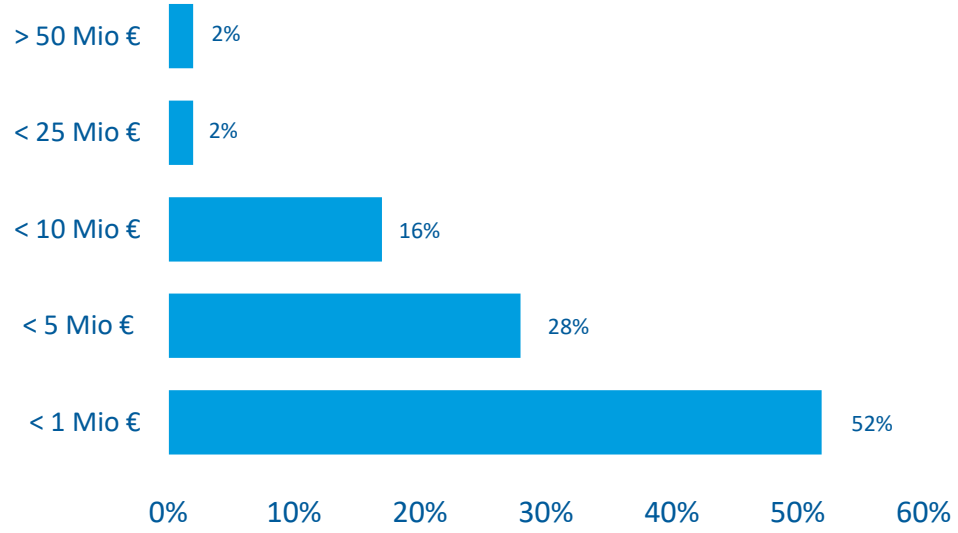
Can we thereby achieve the intended added safety value for patients? Enormous additional expenditures for the healthcare industry.



Investments in the MDR implementation



Financial investments in the MDR implementation | per company



Results of a BVMed survey, May 2021
t = 4 weeks
n = 57 companies

Where do I get more information?

> European Commission – DG Santé
Medical Devices - Sector

> Implementation Rolling Plan

> MDR/IVDR roadmap of competent authorities for medical devices (CAMD)

> Guidelines | MDCG work in progress

> MDR Notified Bodies

?

Dr. Christina Ziegenberg

Deputy Managing Director
Head of Legal and Regulatory Affairs

BVMed - Bundesverband Medizintechnologie e.V.
Reinhardtstr. 29 b, 10117 Berlin
Tel. +49 (0)30 246 255-32
Mobil +49 (0) 173 7055584
ziegenberg@bvmed.de | www.bvmed.de

MDR-Portal: www.bvmed.de/mdr