QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

LISAvienna
life science austria

#REG24
17.10.2024, Wien

QMD Services

IVDR-Update

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

LISAvienna
life science austria

#REG24
17.10.2024, Wien

QMD Services

Am Weg durch den Fristen-Dschungel der Regulatorik

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

LISAvienna
life science austria

#REG24
17.10.2024, Wien

QMD Services

Benannte Stelle
gemäß **Regulation (EU) 2017/746 (IVDR)** und
Regulation (EU) 2017/745 (MDR)

Florian Heffeter

- Seit über 20 Jahre im Gesundheitswesen tätig
- Medizininformatik & Medizinrecht
- Notfallmedizin, MedTech-Industrie, Innovations- u. Strategieberatung
- Seit Mai 2024 CEO der QMD

QMD HoNB

Anni Koubek

- Gründungs-CEO der QMD seit 2018
- Physikerin
- Österreichische Vorreiterin für Qualitätsmanagement in der Medizintechnik
- Ehem. Scientific Director FH Joanneum

QMD Services
Quality | Medical | Devices

Wir sind… 1

… von nur

12

Benannten Stellen

in der Europäischen Union

gemäß beiden Normen:

MDR & IVDR

QMD Services
Quality | Medical | Devices

MDR Angebot der QMD

I CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

Group	Code	
A ACTIVE DEVICES	MDA 0101	
	MDA 0102	
	MDA 0103	
	MDA 0104	
	MDA 0201	
	MDA 0202	
	MDA 0203	
	MDA 0204	*
	MDA 0301	
	MDA 0302	*
	MDA 0303	
	MDA 0304	
	MDA 0305	*
	MDA 0306	*
	MDA 0307	*
	MDA 0308	
	MDA 0309	
	MDA 0310	
	MDA 0311	
	MDA 0312	*
	MDA 0313	
	MDA 0314	
	MDA 0315	*
	MDA 0316	
	MDA 0317	
	MDA 0318	
B NON-ACTIVE DEVICES	MDN 1101	
	MDN 1102	*
	MDN 1103	
	MDN 1104	*
	MDN 1201	
	MDN 1202	*
	MDN 1203	*
	MDN 1204	
	MDN 1205	
	MDN 1206	
	MDN 1207	
	MDN 1208	*
	MDN 1209	
	MDN 1210	
	MDN 1211	*
	MDN 1212	
	MDN 1213	
	MDN 1214	

Code – Coverage for Annexes IX(I), IX(II) and XI(A)

*) Scope under conditions

II HORIZONTAL CODES

Group	Code
Specific characteristics	MDS 1001
	MDS 1002
	MDS 1003
	MDS 1004
	MDS 1005
	MDS 1006
	MDS 1007
	MDS 1008
	MDS 1009
	MDS 1010
	MDS 1011
	MDS 1012
	MDS 1013
Specific technology	MDS 1014
	MDT 2001
	MDT 2002
	MDT 2003
	MDT 2004
	MDT 2005
	MDT 2006
	MDT 2007
	MDT 2008
	MDT 2009
	MDT 2010
	MDT 2011
	MDT 2012
	MDT 2013

Code – Coverage for Annexes IX(I), IX(II) and XI(A)

Code – Limited coverage (aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation)

(For full description of codes see COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185 Annex I

Immer aktuell: das **QMD**-Scope Statement auf NANDO

QMD bietet zusätzliche Services gemäß:

- Artikel 16 (MDR und IVDR): Importeure
- Artikel 22: Systeme und Behandlungseinheiten
- Artikel 117: Medizinprodukte mit Arzneimittelkomponenten als integralen Bestandteil

Seit 14. Mai 2024 die einzige Benannte Stelle unter MDR in Österreich

IVDR Angebot der QMD

I CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

Blood Grouping						Tissue T		Cancer		HumGen			Infections/Immune						Non-infectious pathologies								Control	Class A		
IVR 0101	IVR 0102	IVR 0103	IVR 0104	IVR 0105	IVR 0106	IVR 0201	IVR 0202	IVR 0301	IVR 0302	IVR 0401	IVR 0402	IVR 0403	IVR 0501	IVR 0502	IVR 0503	IVR 0504	IVR 0505	IVR 0506	IVR 0601	IVR 0602	IVR 0603	IVR 0604	IVR 0605	IVR 0606	IVR 0607	IVR 0608	IVR 0609	IVR 0701	IVR 0702	IVR 0801	IVR 0802	IVR 0803

Code — Coverage for Annexes IX(I), IX(II) and XI

II HORIZONTAL CODES

Specific										Technologies										Product verification												Laboratory & Clinical disciplines											
IVS 1001	IVS 1002	IVS 1003	IVS 1004	IVS 1005	IVS 1006	IVS 1007	IVS 1008	IVS 1009	IVS 1010	IVT 2001	IVT 2002	IVT 2003	IVT 2004	IVT 2005	IVT 2006	IVT 2007	IVT 2008	IVT 2009	IVT 2010	IVT 2011	IVP 3001	IVP 3002	IVP 3003	IVP 3004	IVP 3005	IVP 3006	IVP 3007	IVP 3008	IVP 3009	IVP 3010	IVP 3011	IVP 3012	IVP 3013	IVP 3014	IVD 4001	IVD 4002	IVD 4003	IVD 4004	IVD 4005	IVD 4006	IVD 4007	IVD 4008	IVD 4009	IVD 4010	IVD 4011	IVD 4012

Code — Coverage for Annexes IX(I), IX(II) and XI

Code — Limited coverage (aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation)

(For full description of codes see COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185 Annex II

Immer aktuell: das **QMD**- **QMD**-Scope Statement auf NANDO

QMD bietet zusätzliche Services gemäß:

- Artikel 16 (MDR und IVDR): Importeure
- Artikel 22: Systeme und Behandlungseinheiten

Seit 14. Mai 2024 die einzige Benannte Stelle unter MDR in Österreich

QMD Services
Quality | Medical | Devices

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

LISAvienna
life science austria

#REG24
17.10.2024, Wien

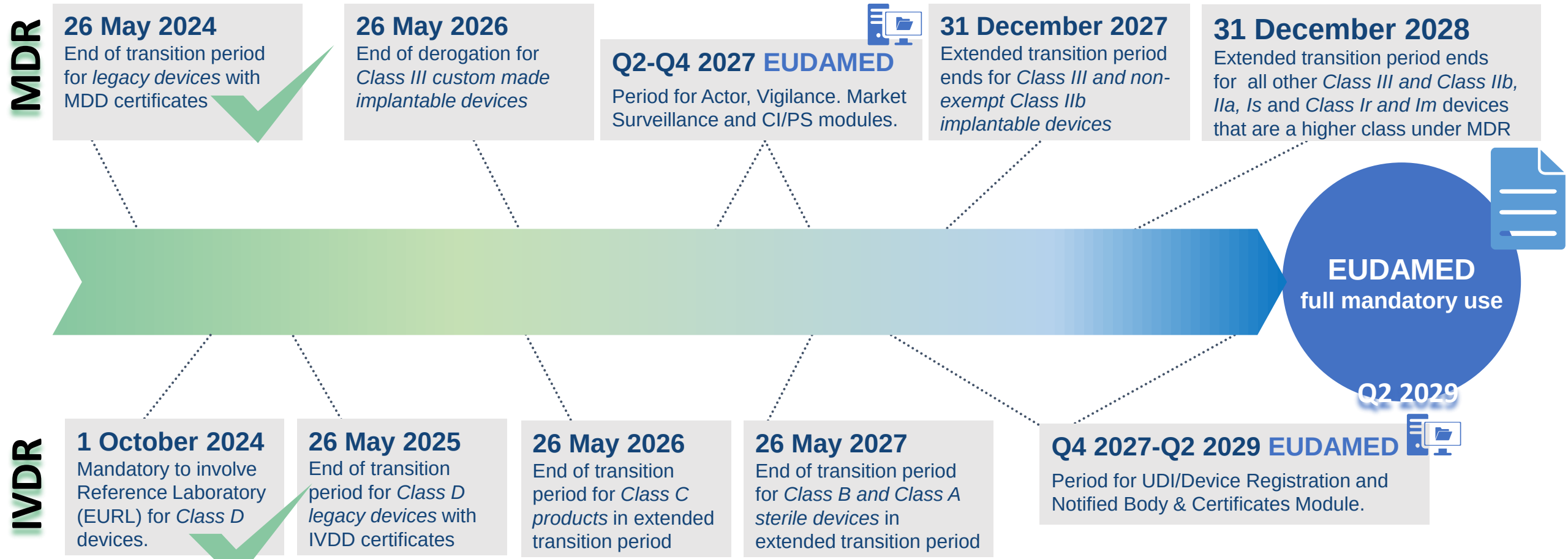
QMD Services

Am Weg durch den Fristen-Dschungel der Regulatorik

AKTUELLE FRISTEN

Relevant dates: Transition to MDR and IVDR *

**) As per current status of published official information on May, 31st, 2024.*
Dates may be subject to change due to revision of regulations in the future.



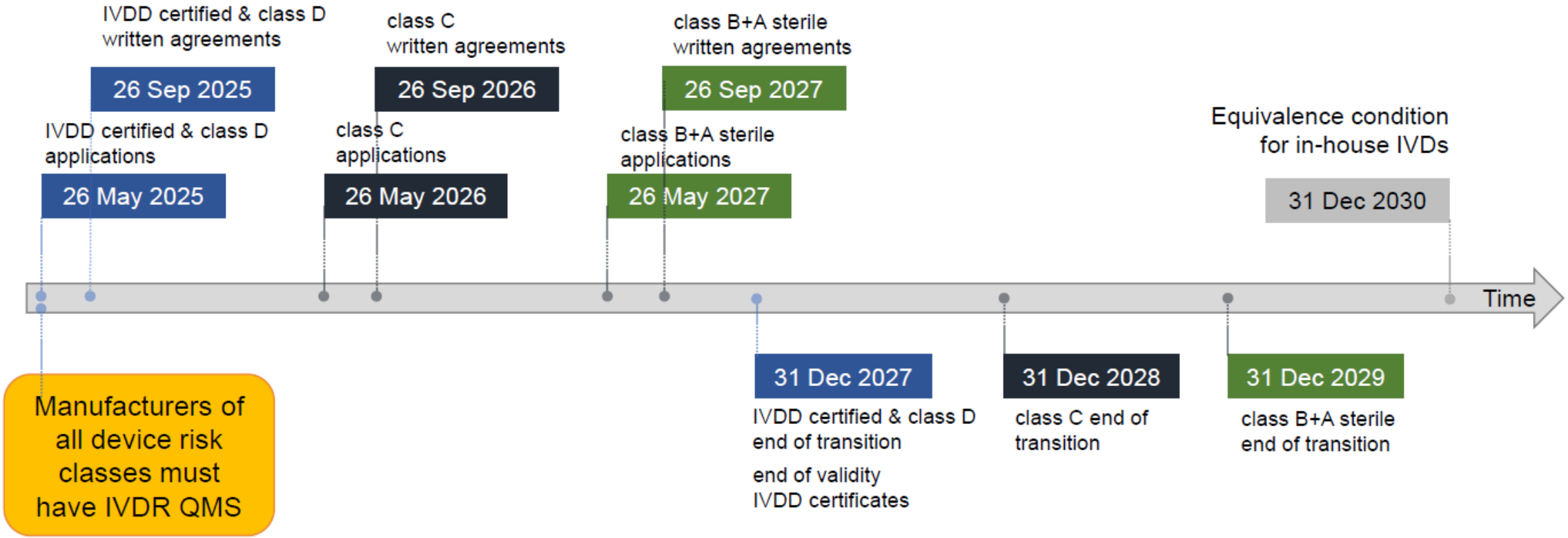
QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

Relevant dates: Transition to IVDR*

acc. Regulation (EU) 2024/1860

*) As per current status of published official information on June, 13th, 2024.
Dates may be subject to change due to revision of regulations in the future.



Source: European Commission

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

Relevant dates: Transition to IVDR*

acc. Regulation (EU) 2024/1860

**) As per current status of published official information on June, 13th, 2024. Dates may be subject to change due to revision of regulations in the future.*

Summary of transitional deadlines described in RE (EU) 2024/1860

Device Class	IVDR compliant QMS	Officially applied to a NB	Signed written agreement with a NB	Transition deadline
IVDD certified devices*	26 May 2025	26 May 2025	26 September 2025	31 December 2027
Class D self-declared	26 May 2025	26 May 2025	26 September 2025	31 December 2027
Class C self-declared	26 May 2025	26 May 2026	26 September 2026	31 December 2028
Class B and A-Sterile self-declared	26 May 2025	26 May 2027	26 September 2027	31 December 2029

Relevant dates: Transition to IVDR*

acc. Regulation (EU) 2024/1860

**) As per current status of published official information on June, 13th, 2024. Dates may be subject to change due to revision of regulations in the future.*

Which devices can benefit from the extended transition period?

Devices that meet the following criteria:

- Compliance with IVD Directive 98/79/EC;
- Compliance with the IVDR provisions related to PMS and vigilance;
- No significant changes can be made;
- Implementation of an IVDR compliant Quality Management System by 26th May 2025;
- A formal conformity assessment application is made with a notified body before:
  - 26 May 2025 (class D)
  - 26 May 2026 (class C)
  - 26 May 2027 (class B and class A sterile)
- A written agreement is in place between the manufacturer and notified body before:
  - 26 September 2025 (class D),
  - 26 September 2026 (class C) or
  - 26 September 2027 (class B and class A sterile).

Note: The change of transitional provisions only applies to devices requiring the involvement of a notified body for their conformity assessment under IVDR.

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

LISAvienna
life science austria

#REG24
17.10.2024, Wien

QMD Services

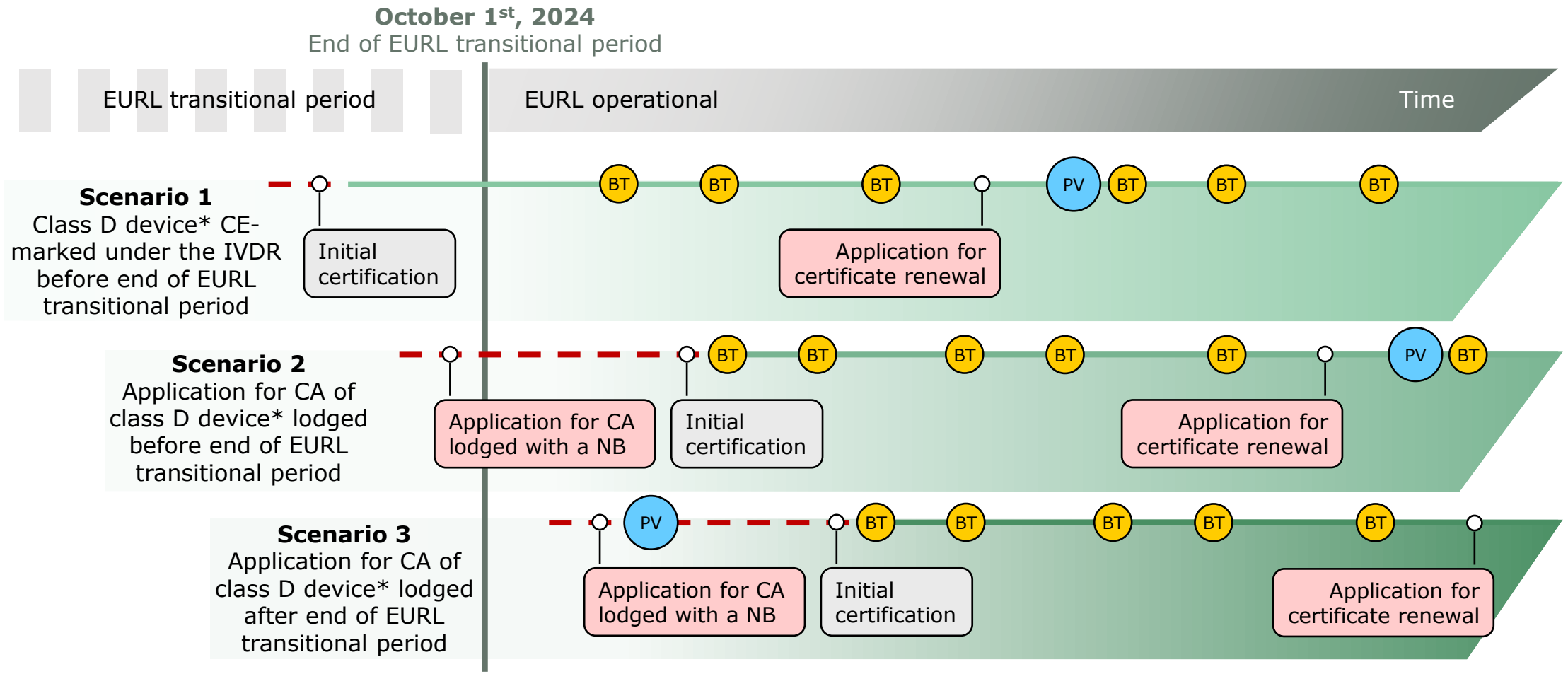
Am Weg durch den (Fristen-)Dschungel der Regulatorik

EURLs

European Reference Labs (EURL)

- Seit 1. Oktober 2024 sind EURLs für die Performance Evaluation von IVDs der Klasse D verpflichtend miteinzubeziehen!
  - Ende der „EURL Transitional Period“

Class D IVD Devices: Transitional provisions for EURL performance verification and batch testing under the IVDR



* intended use of class D device in scope of designation of EU reference laboratory

BT batch verification by EURL

PV performance verification by EURL

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

Coverage of EURL Designations

- 5 European Union Reference Laboratories (EURLs) designated via Implementing Act 2023/2713 (December 2023)
- 4 categories of Class D devices covered
  - Hepatitis and retroviruses,
  - Herpesviruses,
  - Bacterial agents,
  - Respiratory viruses that cause life-threatening diseases.
- At the moment, no EURL has been designated for the remaining technical categories of Class D devices:
  - Arboviruses,
  - Haemorrhagic fever and other biosafety level 4 viruses,
  - Parasites,
  - Blood grouping.

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

LISAvienna
life science austria

#REG24
17.10.2024, Wien

QMD Services

Am Weg durch den (Fristen-)Dschungel der Regulatorik

BEWÄLTIGUNGSSTRATEGIEN IM PROZESS

Monitoring of the Availability of In Vitro Diagnostic Medical Devices in the EU

European Commission

Gesundheit Österreich GmbH

[MD Availability Dashboard 1.3](#)

Last Update: 6.7.2024

Select stakeholder

Notified Bodies (NBs)

Select date of survey

03/23 | 06/23 | 10/23 | 02/24

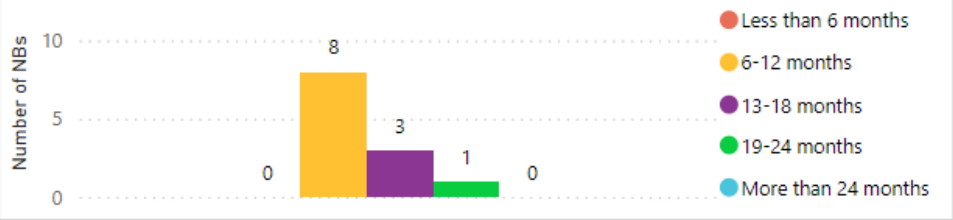
100

Response rate of survey in %

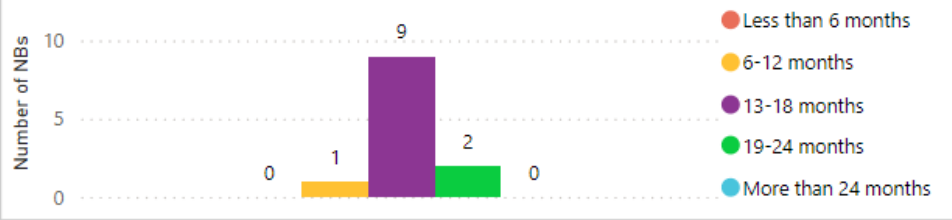
Completeness of applications in number of notified bodies (IVDR)

Number of applications refused by reason (IVDR)

Time needed to issue QMS certificate only (IVDR)



Time needed to issue QMS and product certificates (IVDR)



QMD Services
Quality | Medical | Devices

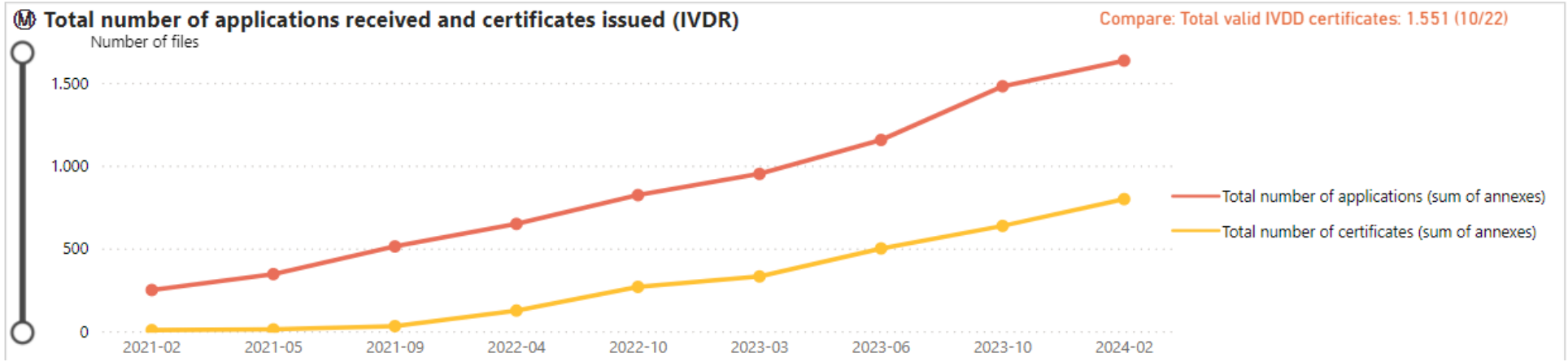
Monitoring of the Availability of In Vitro Diagnostic Medical Devices in the EU

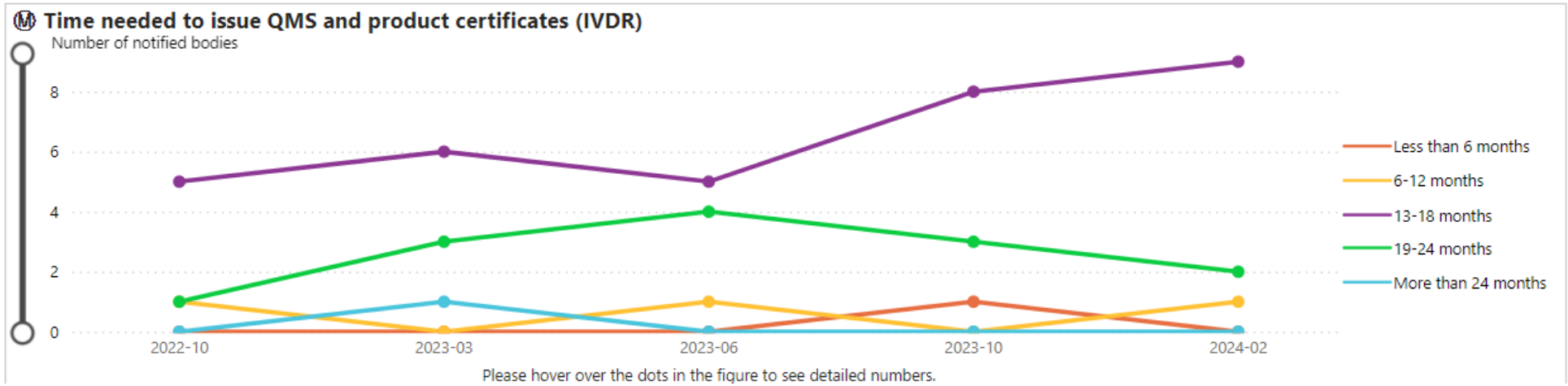
European Commission

Gesundheit Österreich GmbH

[MD Availability Dashboard 1.3](#)

Last Update: 6.7.2024



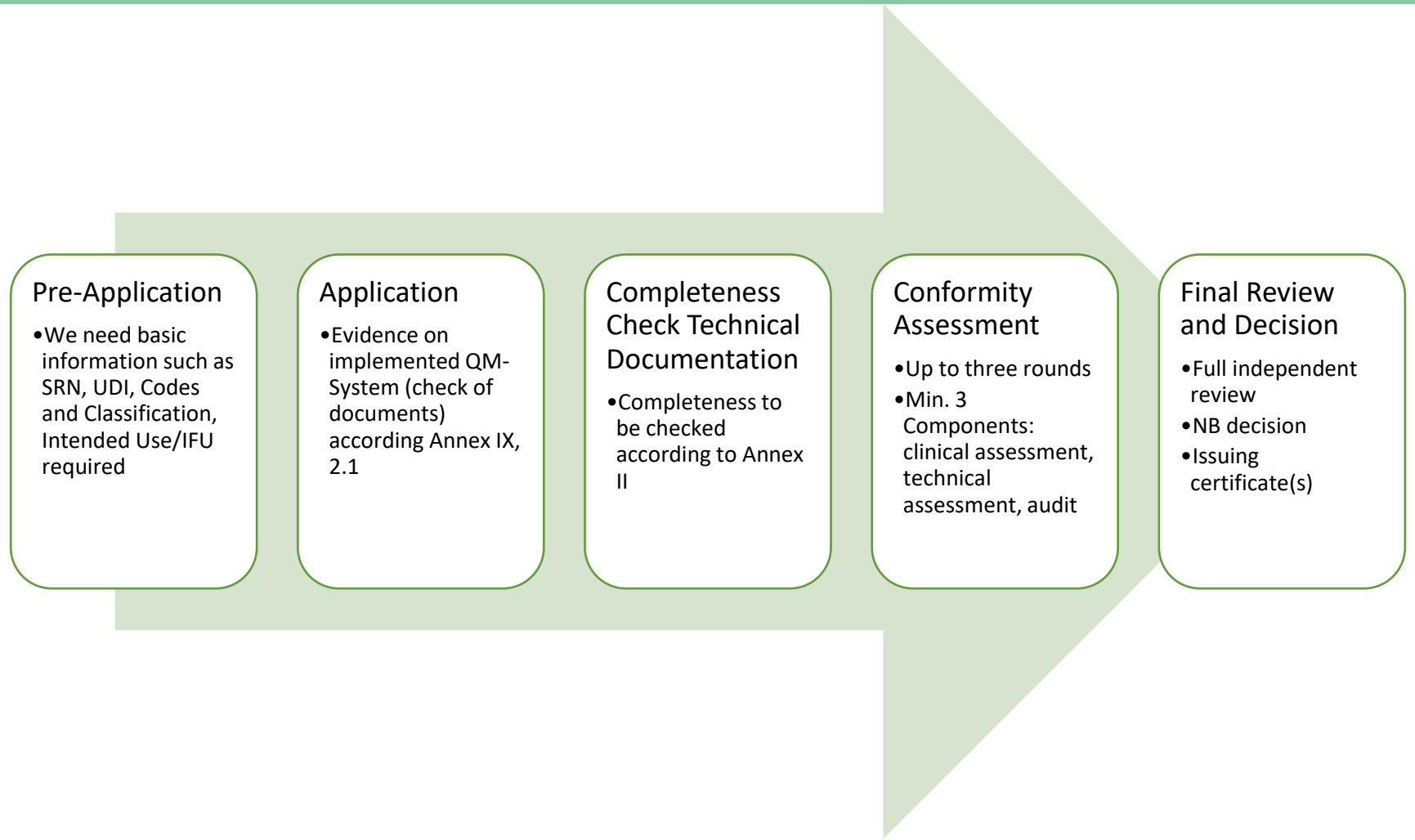


QMD Services
Quality | Medical | Devices

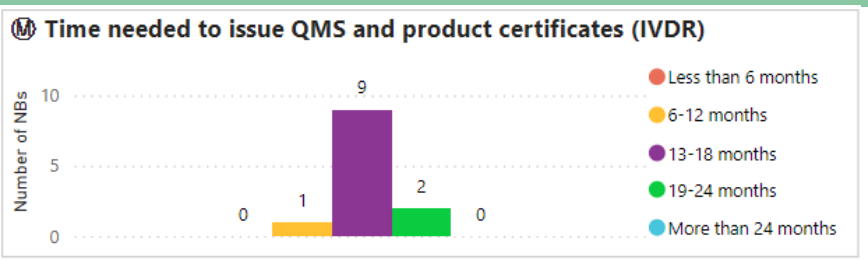
Some notes on process specifics

- All notified bodies follow the same rules
- There is rough agreement on duration of different phases of conformity assessment (Team NB Code-of-Conduct)
- Our special approach of service delivery:
  - Intens and personal communication througout the whole process
  - We charge a pre-application and an application fee – advance payment for intense preparation effort in that phase
  - We offer structured dialog, starting with pre-application
  - We cannot offer any consultancy!

Overview of our conformity assessment process



Typical time-lines



Quelle: EU MD Availability Dashboard (02/24)

Pre-Application
- We need basic information such as SRN, UDI, Codes and Classification, Intended Use/IFU required

1-2 months

Application
- Evidence on implemented QM-System (check of documents) according Annex IX, 2.1

1-3 months

Completeness Check Technical Documentation
- Completeness to be checked according to Annex II

1 month

Conformity Assessment
- Up to three rounds
- Min. 3 Components: clinical assessment, technical assessment, audit

3-6 months (more for high risk class)

Final Review and Decision
- Full independent review
- NB decision
- Issuing certificate(s)

1 month

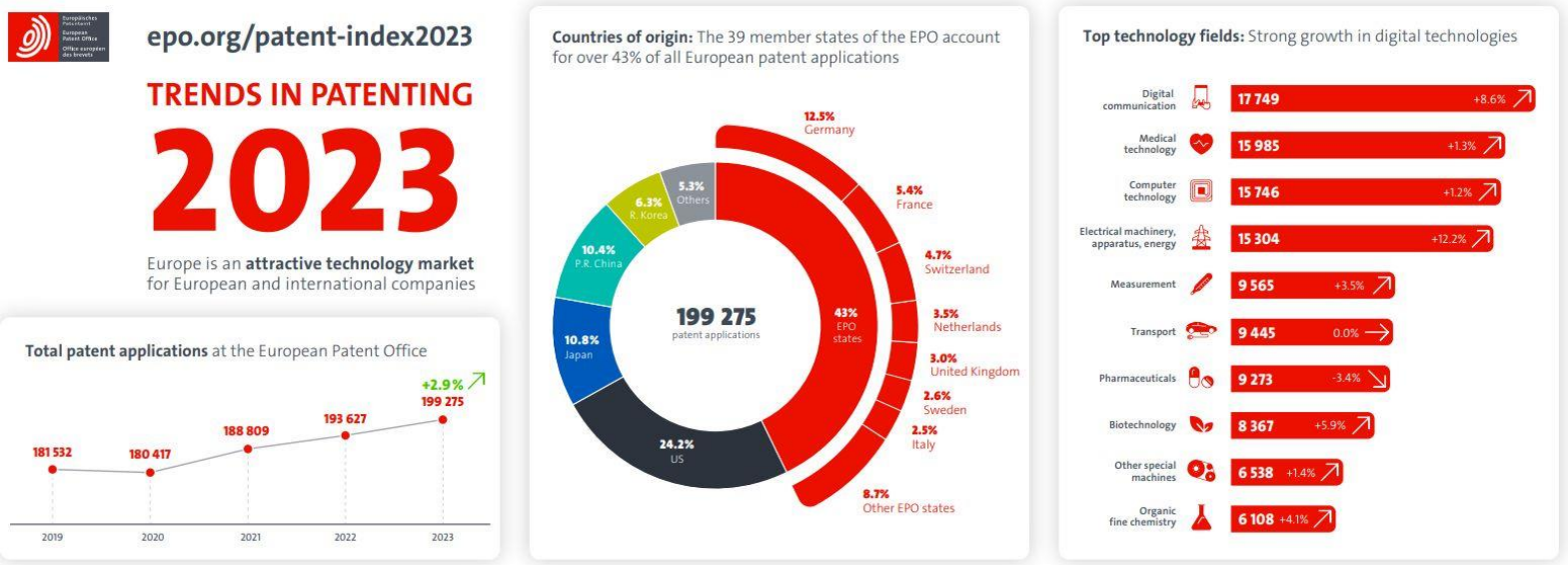
QMD Services
Quality | Medical | Devices

General Tipps for swift process

- For each phase:
  - Prepare the requested information complete and according to instructions
  - We will give you clear guidance, but we know this is tedious
- **All iterations lead to**
  - delays on our side, as we cannot keep our planned project slots
  - higher costs for re-checks
  - longer time to market for your product

"Your technical documentation can make or break your conformity assessment process." *– Some Director Quality & Regulatory Affairs for MDR*

SMEs power MedTech Innovation in Europe



There are more than 37,000 medical technology companies in Europe. The highest number of them are based in Germany, followed by Italy, the UK, Poland, Sweden and Switzerland. Small and medium-sized companies (SMEs) make up around 90% of the medical technology industry, the majority of which employs less than 50 people (small and micro-sized companies)[5].

37,000
medical technology companies in Europe
90% SMEs

QMD Services
Quality | Medical | Devices

Innovative products…

…get certified with **QMD**!

QMDservices.com

QMD Services
Quality | Medical | Devices

Bleiben wir in Verbindung

QMD Services
Quality | Medical | Devices

Florian Heffeter
CEO

QMD Services GmbH
Headquarters: Zelinkagasse 10/3, 1010 Vienna, Austria
Operations Office: Am Winterhafen 1, 4020 Linz, Austria

Tel.: +43 1 533 0077
Mobile: +43 664 820 29 83
E-Mail: Florian.Heffeter@qmdservices.com