QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

QMD Services

Notified Body
according **Regulation (EU) 2017/746 (IVDR)** and
Regulation (EU) 2017/745 (MDR)

公告机构
根据《欧盟法规 (EU) 2017/746（IVDR）》与《欧盟法规 (EU) 2017/745（MDR）》
指定

We are… 1

… out of

14

Notified Bodies

in the European Union

我们是14家欧盟公告机构之一根据《医疗器械法规》（MDR）与《体外诊断医疗器械法规》（IVDR）授权指定

designated according:

MDR & IVDR

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We are… 1

… of

the youngest

Notified Bodies

in the European Union

designated according:

MDR & IVDR

我们是欧盟中最年轻的公告机构之一

已根据：

《医疗器械法规》（MDR）

《体外诊断医疗器械法规》（IVDR）

完成指定

QMD Services

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We are the 1

… and

only

Notified Body

in Austria

designated according:

MDR & IVDR

我们是奥地利
唯一依据MDR
与IVDR指定的
公告机构

QMD Services
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Our CEOs

Florian Heffeter

- >20 years in health sector
- Medical informatics, medical law
- Since May 2024: CEO of QMD
- 在医疗健康领域拥有超过20年经验
- 专业背景：医学信息学、医疗法规
- 自2024年5月起担任QMD首席执行官

Anni Koubek

- Founding-CEO of QMD since 2018
- Physicist, Scientist, QM Professional
- Past Scientific Director of University of applied sciences
- 自2018年起担任QMD创始CEO
- 物理学家、科学家、质量管理专业人士
- 曾任应用科技大学科学总监

QMD Services
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QMD Competence Hub
QMD 能力

- Team composed of experts with long-term previous notified body experience
- Employees in four European countries and UK
- Over 40 experts for conformity assessment tasks authorised
- 团队成员拥有长期公告机构从业经验
- 员工分布于4个欧洲国家及英国
- 超过40名专家被授权执行合格评定任务

From Austria for Europe and the whole globe!

从奥地利出发，服务欧洲及全球

- Broad client base throughout Europe
- 客户群覆盖整个欧洲地区

QMD Services
Quality | Medical | Devices

From Austria for Europe and the whole globe!

从奥地利出发，服务欧洲及全球

- Global client base supported through partners
- 全球主要地区的服务覆盖，包括北美、欧洲、中东、亚太与大洋洲

QMD Services
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QMD focus areas and expertise
QMD 的核心领域与专业能力

- Perfect partner for
  - innovative products
- SMEs and start-ups
- with client-oriented high quality service
- Future oriented specific expertise in software and medical AI
- International approach: working language is English
- Transparency: all certificates published in EUDAMED
- 是创新产品、中小企业和初创企业的理想合作伙伴
- 提供以客户为导向的高质量服务
- 聚焦未来导向的专业能力，特别是在软件与医疗人工智能方面
- 国际化运作：工作语言为英语
- 透明公开：所有证书均发布在 EUDAMED 数据库中

From Austria for Europe and the whole globe!

从奥地利出发，服务欧洲及全球

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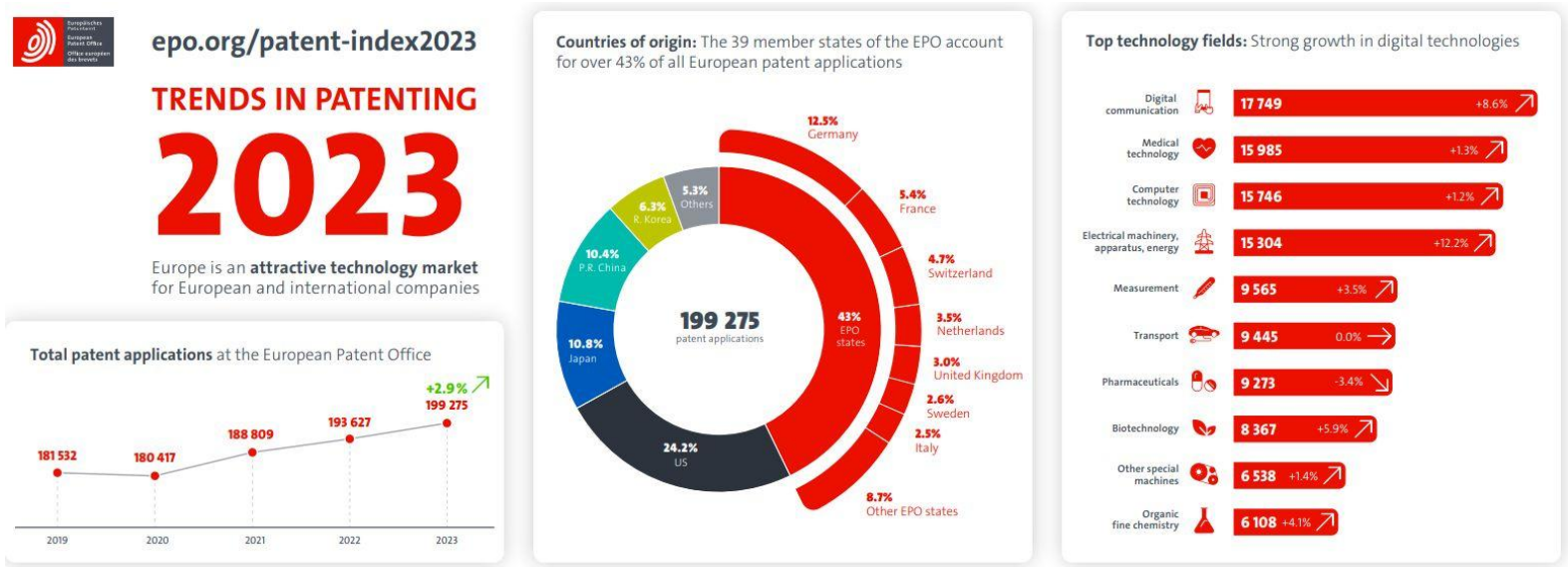
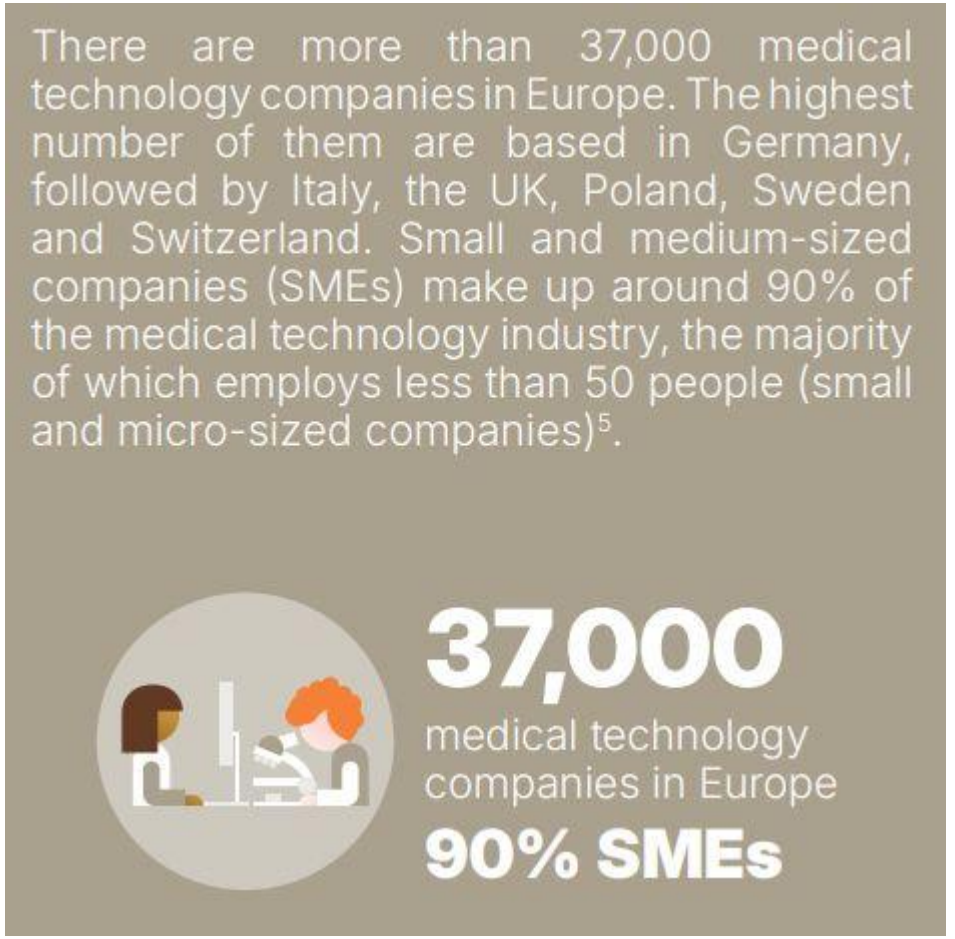
SMEs are the key drivers of MedTech innovation in Europa
中小企业是推动欧洲医疗技术创新的关键力量





- 欧洲现有超过 37,000 家医疗技术企业
- 数量最多的国家依次为德国、意大利、英国、波兰、瑞典和瑞士
- 中小企业（SMEs）约占整个医疗技术行业的 90%，其中大多数企业员工人数少于 50 人（属于小微企业）

MDR scope of QMD
QMD 的 MDR 指定范围

I CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

Group	Code	Covered (green)	Scope under conditions
A ACTIVE DEVICES	MDA0101		
A ACTIVE DEVICES	MDA0102		
A ACTIVE DEVICES	MDA0103		
A ACTIVE DEVICES	MDA0104		
A ACTIVE DEVICES	MDA0201		
A ACTIVE DEVICES	MDA0202		
A ACTIVE DEVICES	**MDA0203**	Code	
A ACTIVE DEVICES	**MDA0204**	Code	*
A ACTIVE DEVICES	MDA0301		
A ACTIVE DEVICES	**MDA0302**	Code	*
A ACTIVE DEVICES	MDA0303		
A ACTIVE DEVICES	MDA0304		
A ACTIVE DEVICES	**MDA0305**	Code	*
A ACTIVE DEVICES	**MDA0306**	Code	*
A ACTIVE DEVICES	**MDA0307**	Code	*
A ACTIVE DEVICES	MDA0308		
A ACTIVE DEVICES	MDA0309		
A ACTIVE DEVICES	MDA0310		
A ACTIVE DEVICES	MDA0311		
A ACTIVE DEVICES	**MDA0312**	Code	*
A ACTIVE DEVICES	MDA0313		
A ACTIVE DEVICES	MDA0314		
A ACTIVE DEVICES	**MDA0315**	Code	*
A ACTIVE DEVICES	MDA0316		
A ACTIVE DEVICES	MDA0317		
A ACTIVE DEVICES	**MDA0318**	Code	
B NON-ACTIVE DEVICES	**MDN1101**	Code	
B NON-ACTIVE DEVICES	**MDN1102**	Code	*
B NON-ACTIVE DEVICES	MDN1103		
B NON-ACTIVE DEVICES	**MDN1104**	Code	*
B NON-ACTIVE DEVICES	**MDN1201**	Code	
B NON-ACTIVE DEVICES	**MDN1202**	Code	*
B NON-ACTIVE DEVICES	**MDN1203**	Code	*
B NON-ACTIVE DEVICES	MDN1204		
B NON-ACTIVE DEVICES	MDN1205		
B NON-ACTIVE DEVICES	MDN1206		
B NON-ACTIVE DEVICES	MDN1207		
B NON-ACTIVE DEVICES	**MDN1208**	Code	*
B NON-ACTIVE DEVICES	MDN1209		
B NON-ACTIVE DEVICES	MDN1210		
B NON-ACTIVE DEVICES	**MDN1211**	Code	*
B NON-ACTIVE DEVICES	MDN1212		
B NON-ACTIVE DEVICES	MDN1213		
B NON-ACTIVE DEVICES	MDN1214		

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

*) Scope under conditions

II HORIZONTAL CODES

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

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

Code (orange) — 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
详见：欧盟执行法规 EU 2017/2185 附录 I

Check our detailed scope statement in [NANDO](#)

- 请访问 NANDO 数据库查看我们的详细指定范围

QMD offers additionally QMD 还可提供以下附加服务：

- Article 16 (MDR and IVDR): Importers 第16条（MDR/IVDR）：进口商符合性评估
- Article 22: (MDR) Systems and Procedure Packs 第22条（MDR）：系统与程序包审核
- Article 117: (MDR) medicinal substances with an integral medical device 第117条（MDR）：含药医疗器械相关审核

Since 14. Mai 2024: the ony Notified Body according MDR in Austria

自2024年5月14日起：QMD成为奥地利唯一根据MDR指定的公告机构

QMD Services
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IVDR scope of QMD
QMD 的 IVDR 指定范围

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		
MR0101	MR0102	MR0103	MR0104	MR0105	MR0106	MR0201	MR0202	MR0301	MR0302	MR0401	MR0402	MR0403	MR0501	MR0502	MR0503	MR0504	MR0505	MR0506	MR0601	MR0602	MR0603	MR0604	MR0605	MR0606	MR0607	MR0608	MR0609	MR0701	MR0702	MR0801	MR0802	MR0803

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

II HORIZONTAL CODES

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

Check our detailed scope statement in NANDO

- 查看详细指定范围请访问 NANDO

- **QMD offers additionally** QMD 还可提供：
  - Article 16 (IVDR): Importers 第16条（IVDR）：进口商符合性评估

Seit 23. Dezember 2022
die einzige
Benannte Stelle
unter IVDR in Österreich

自2022年12月23日起，QMD成为奥地利唯一一家根据IVDR指定的公告机构

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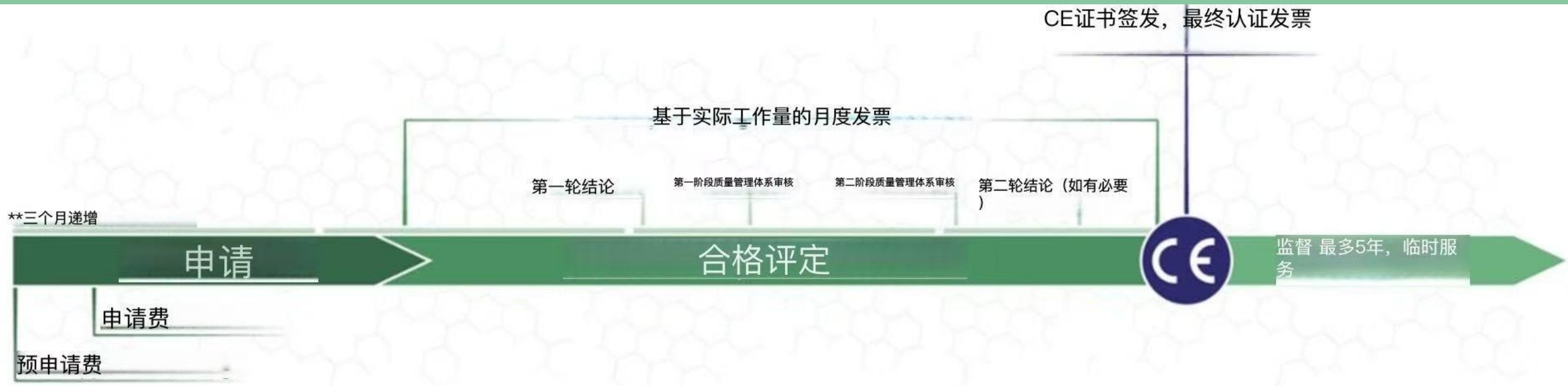
BECAUSE PATIENT SAFETY MATTERS.

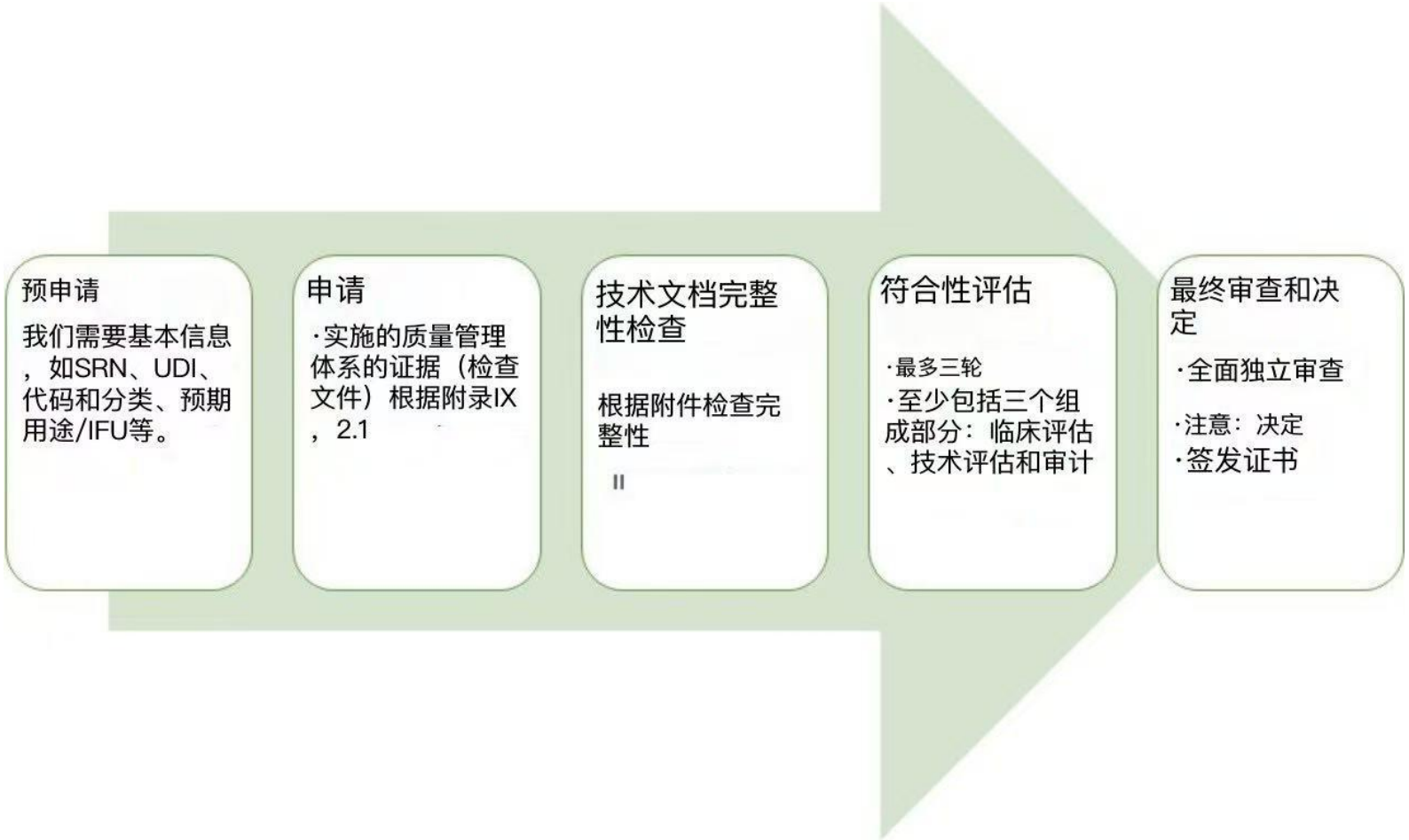
Conformity Assessment with QMD Services
与 QMD Services 开展符合性评定工作



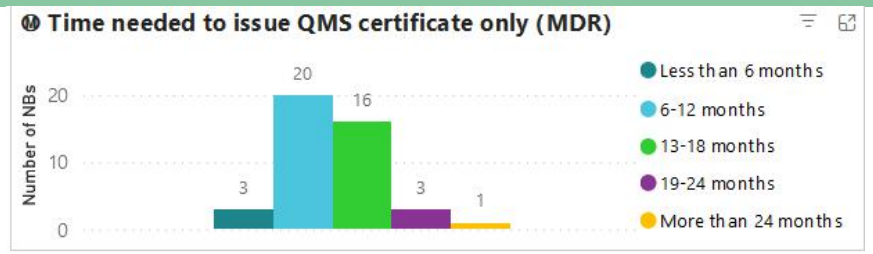

EU Quality Management System Certificate
REGULATION (EU) 2017/746, Annex IX Chapter I and III
Test Manufacturer GmbH
DRAFT CERTIFICATE

Sample certificate: content will vary depending on regulation, risk class and CA route
证书样本：内容将根据适用法规、风险等级及符合性评定路径而有所不同

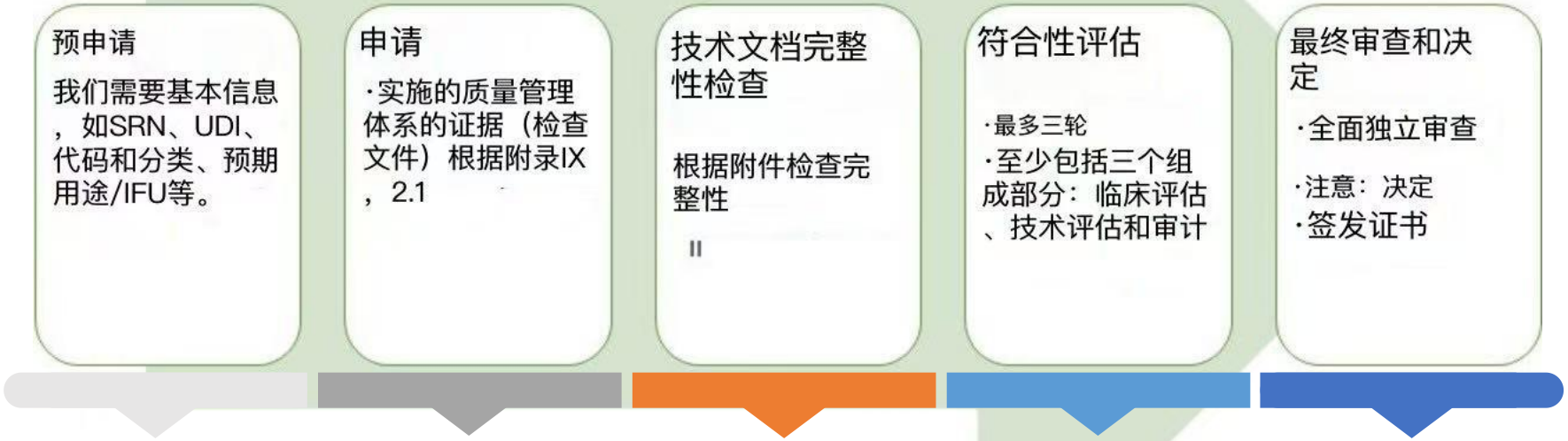
Overview of our Conformity Assessment process
我们的符合性评定流程概览



Typical time-line
典型评审时间线展示



Quelle: EU MD Availability Dashboard



1-2	1-2	1	3-6	1
Months月	Months月	Month月	Months月 (more for high risk class 高风险适用）	Month月

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Some notes of process specifics
流程说明要点

- 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 communication
  - We offer structured dialog, starting with pre-application
  - We cannot offer any consultancy!
  - We charge a pre-application and an application fee – advance payment for executed effort in that phase
- 所有公告机构遵循统一规则
- 对于各阶段所需时间，业界已有大致共识（基于Team NB行为准则）
- QMD的服务交付特色如下：
  - 密集沟通
  - 提供结构化沟通流程，从预申请开始
  - 不提供咨询服务
  - 收取预申请费与正式申请费（用于支付已开展工作的成本）

General Tipps for swift process
提升流程效率的建议

- 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

- 每一阶段请注意：
  - 准备完整、符合要求的资料
  - 我们会提供清晰指引，但也理解过程繁琐
- **每一次返工都会导致：**
  - 项目延期（我们无法保留原定审核时段）
  - 补审成本上升
  - 产品上市周期延长

Relevant dates: Transition to MDR and IVDR *
关键时间节点：向 MDR 与 IVDR 的过渡

*) 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.

MDR

26 May 2024
End of transition period for *legacy devices* with MDD certificates
2024年5月26日
MDD证书遗留器械的过渡期结束

26 May 2026
End of derogation for *Class III custom made implantable devices*
2026年5月26日
III类定制植入器械的豁免期结束

Q2-Q4 2027 EUDAMED
Period for Actor, Vigilance. Market Surveillance and CI/PS modules.
2027年第2季度至第4季度：EUDAMED
EUDAMED模块上线期（包括参与者、监管、市场监测及CI/PS模块）

31 December 2027
Extended transition period ends for *Class III and non-exempt Class IIb implantable devices*
2027年12月31日
III类器械与部分非豁免的IIb类植入器械的延长期结束

31 December 2028
Extended transition period ends for all other *Class III and Class IIb, IIa* and *Class Ir and Im* devices that are a higher class under the MDR
2028年12月31日
其余所有III类、IIb、IIa类器械，以及根据MDR被重新归类为更高风险等级的Ir与Im类器械的延长期结束

EUDAMED full mandatory use
EUDAMED 完全强制使用时间
Q2 2029

IVDR

•1 October 2024
Mandatory to involve Reference Laboratory (EURL) for *Class D* devices.
• 2024年10月1日
D类器械必须强制引入欧盟参考实验室（EURL）

31 Dec 2027**
End of transition period for *Class D legacy devices* with IVDD certificates
2027年12月31日
D类遗留器械（持有IVDD证书）过渡期结束

31 Dec 2028**
End of transition period for *Class C products* in extended transition period
2028年12月31日
C类产品在延长期内的过渡期结束

31 May 2029*
End of transition period for *Class B and Class A sterile devices* in extended transition period
2029年5月31日
B类器械和A类无菌器械在延长期内的过渡期结束

Q4 2027-Q2 2029 EUDAMED
Period for UDI/Device Registration and Notified Body & Certificates Module.
2027年第4季度至2029年第2季度：EUDAMED
EUDAMED模块上线期（UDI/器械注册、公告机构与证书模块）

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** devices complying with conditions outlined in RE (EU) 2024/1860

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创新产品

…get certified with **QMD**!

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获取权威认证！

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