Johner Institut

Implementierung der MDR: Aspekte für die bevorstehende Evaluierung

Lübeck Summer Academy 2023

- seit 2006 am **Johner Institut** (Beratung)
- 2012 Ausgründung der **Medsoto GmbH** (toolunterstützte Entwicklung von Medizinprodukten, ALM/Polarion)
- seit 2021 **Regulatory Scientist** (Digitalisierung)
- seit 2022 **Promotion** im Bereich Medical Device Regulatory Science

Johner Institut

medsoto
MEDICAL SOFTWARE TOOLS

TECHNISCHE UNIVERSITÄT DRESDEN

Dipl.-Ing. Sven Wittorf, M.Sc.

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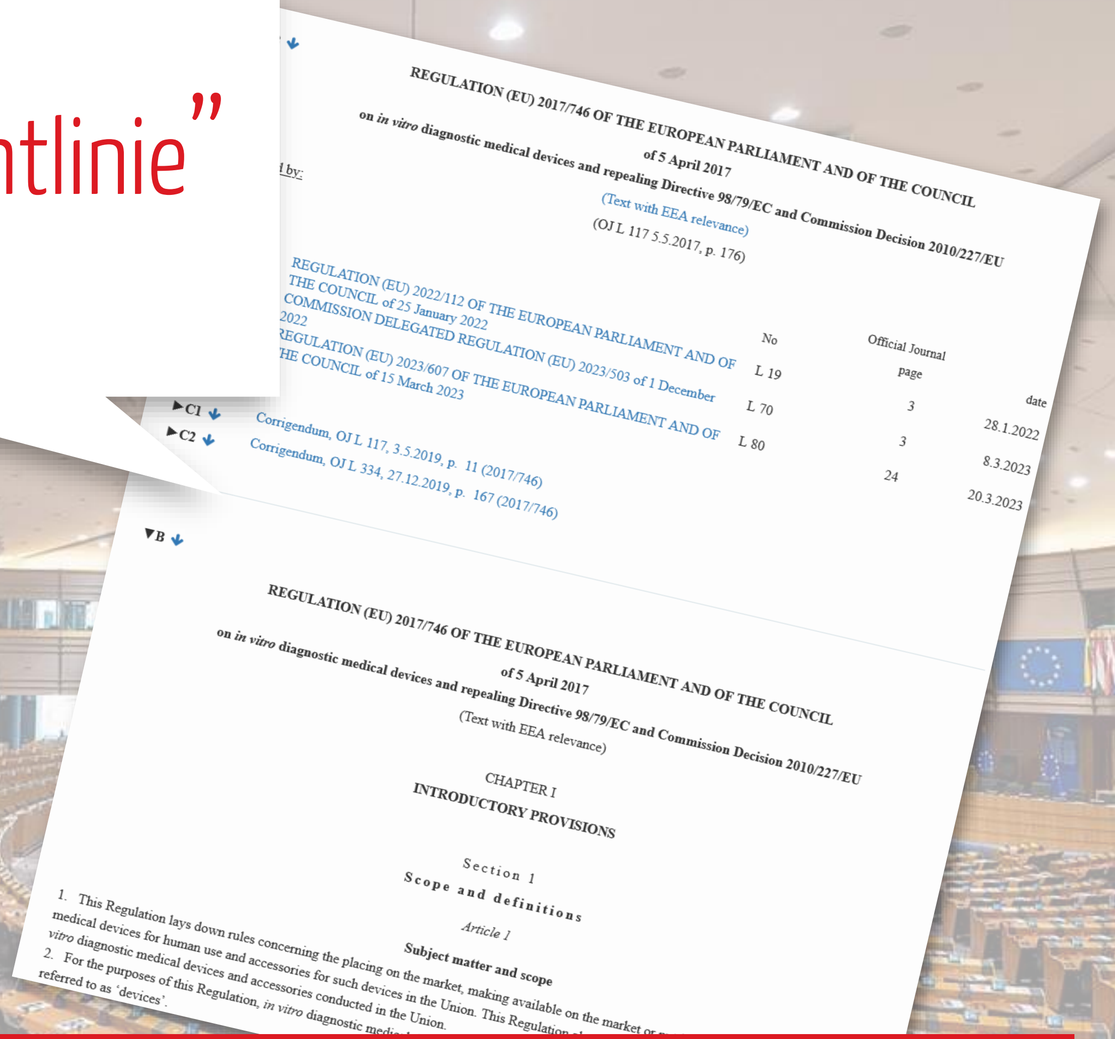
“Ich Vermisse Die Richtlinie”



REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
(Text with EEA relevance)
(OJ L 117 5.5.2017, p. 176)

l by:

		No	Official Journal page	date
	REGULATION (EU) 2022/112 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 January 2022	L 19	3	28.1.2022
	COMMISSION DELEGATED REGULATION (EU) 2023/503 of 1 December 2022	L 70	3	8.3.2023
	REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023	L 80	24	20.3.2023

▼C1 Corrigendum, OJ L 117, 3.5.2019, p. 11 (2017/746)
▼C2 Corrigendum, OJ L 334, 27.12.2019, p. 167 (2017/746)

▼B

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
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CHAPTER I
INTRODUCTORY PROVISIONS

Section 1
Scope and definitions

Article 1
Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or
medical devices for human use and accessories for such devices in the Union. This Regulation
vitro diagnostic medical devices and accessories conducted in the Union.
2. For the purposes of this Regulation, *in vitro* diagnostic medi
referred to as ‘devices’.

In-Vitro-Diagnostika-Verordnung – IVDR

Erstarren

Flucht

Angriff

Bildquelle: dreamerve / 123rf.com

“Mach Dinge richtig!”

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
(Text with EEA relevance)
(OJ L 117 5.5.2017, p. 1)

REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020
COMMISSION DELEGATED REGULATION (EU) 2023/502 of 1 December 2022
REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023

Corrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745)
Corrigendum, OJ L 334, 27.12.2019, p. 165 (2017/745)

	No	page	date
	L 130	18	24.4.2020
	L 70	1	8.3.2023
	L 80	24	20.3.2023

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CHAPTER I
SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.
2. This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology. The common specifications listed in Annex XVI shall address, at least, application of risk management as set out in Annex I, necessary, clinical evaluation regarding safety.

The necessary common specifications shall be adopted by
into force or from ▶M1 26 May 2021

Medizinprodukteverordnung – MDR

Gesetzliche Anforderungen an Medizinprodukte

Sicherheit

Leistungsfähigkeit

Gesetzliche Anforderungen an Medizinprodukte?

Sicherheit

Leistungsfähigkeit

Verfügbarkeit?

Bezahlbarkeit?

Sicherheit

Sicherheit (/ Leistung)

Wie werden diese Ziele erreicht?

Sicherheit	**effektive** Regulierung
Leistungsfähigkeit	**effektive** Entwicklung
Verfügbarkeit?	**effiziente** Regulierung
Bezahlbarkeit?	**effiziente** Entwicklung

▶B
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
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Amended by:

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▶M1	REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020	L 130	18	24.4.2020
▶M2	COMMISSION DELEGATED REGULATION (EU) 2023/502 of 1 December 2022	L 70	1	8.3.2023
▶M3	REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023	L 80	24	20.3.2023

Corrected by:

▶C1 Corrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745)
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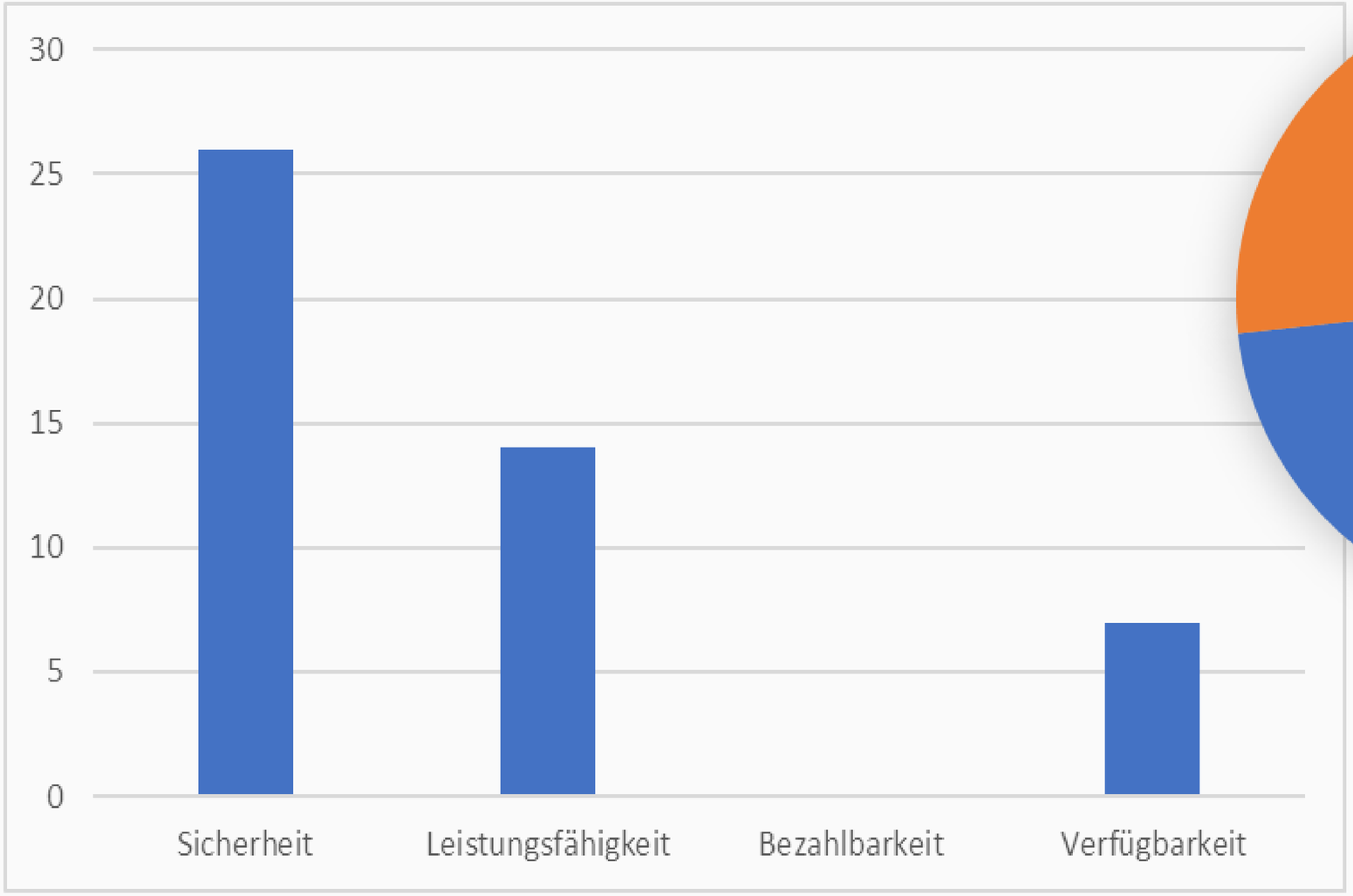
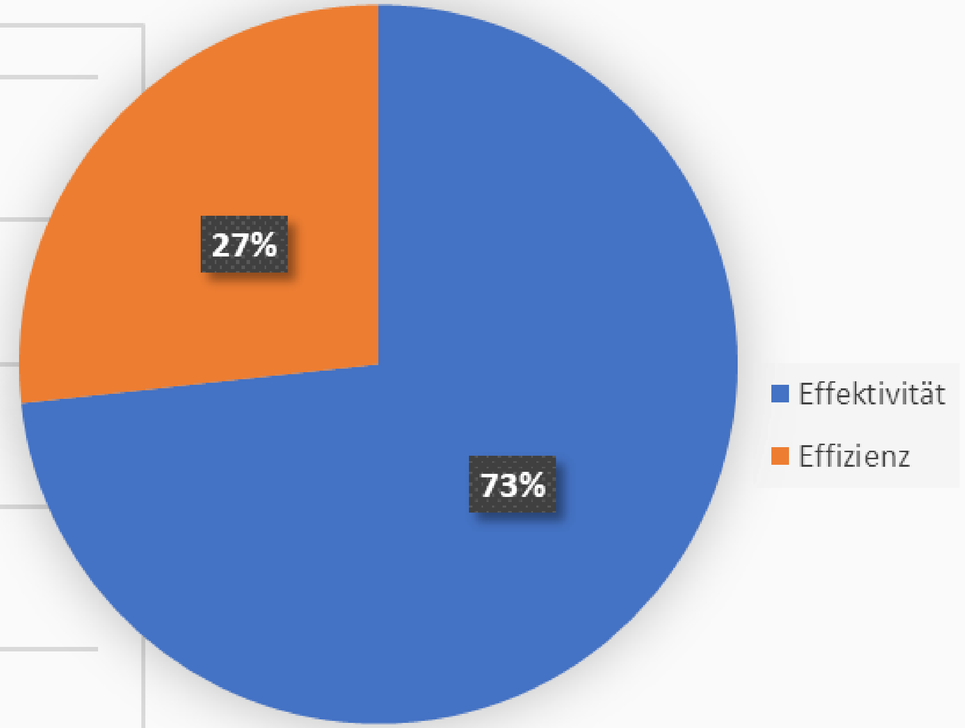
The necessary common specifications shall be adopted by ... into force or from ▶M1 26 May 2021 ...
Notwithstanding Article 12...
to Directive...

Ziele & Begründungen für die MDR

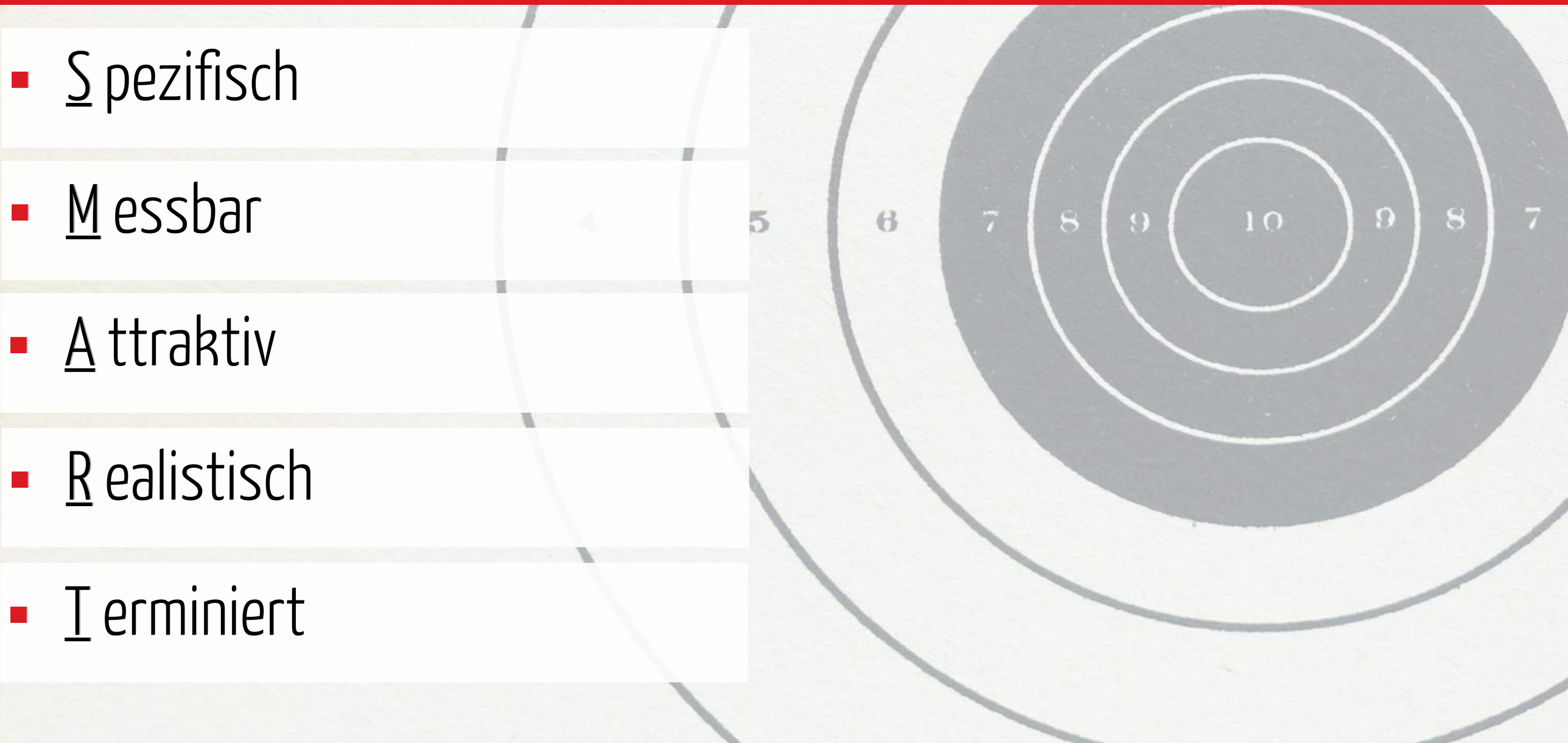
Ziele & Begründungen aus dem Vorwort der MDR





Gute Ziele sind …

- Spezifisch
- Messbar
- Attraktiv
- Realistisch
- Terminiert



Anzahl der neu angezeigten Produkte steigt

Anzahl der innovativen Produkte steigt

Anzahl der Vorkommnisse sinkt

Anzahl der neuen Hersteller / Startups steigt

Anzahl der Insolvenzen sinkt

S.M.A.R.T.e Ziele

World Medical Device Summit,
Konstanz
May, 16th-17th 2023

Wirtschafts- und Staatsministerien

Bundesgesundheitsministerium

ZLG

EU-Kommission

FDA

Goals of WMDS 2023

The goals of the WMDS 2023 are:

- Achieving common understanding of current situation
- Evaluating results from WMDS 2022 and assessing the status of the digitalization of regulatory processes
- Identifying needs of the medical device ecosystem that regulation must address
- Generating ideas how regulation can meet these needs and learning from other domain

Hersteller

Herstellervertreter

Benannte Stellen

Anwender (Mediziner)

World Medical Device Summit

- **Digitalization of regulatory processes**
  The status quo

World Medical Device Summit (WMDS)

WMDS 2022

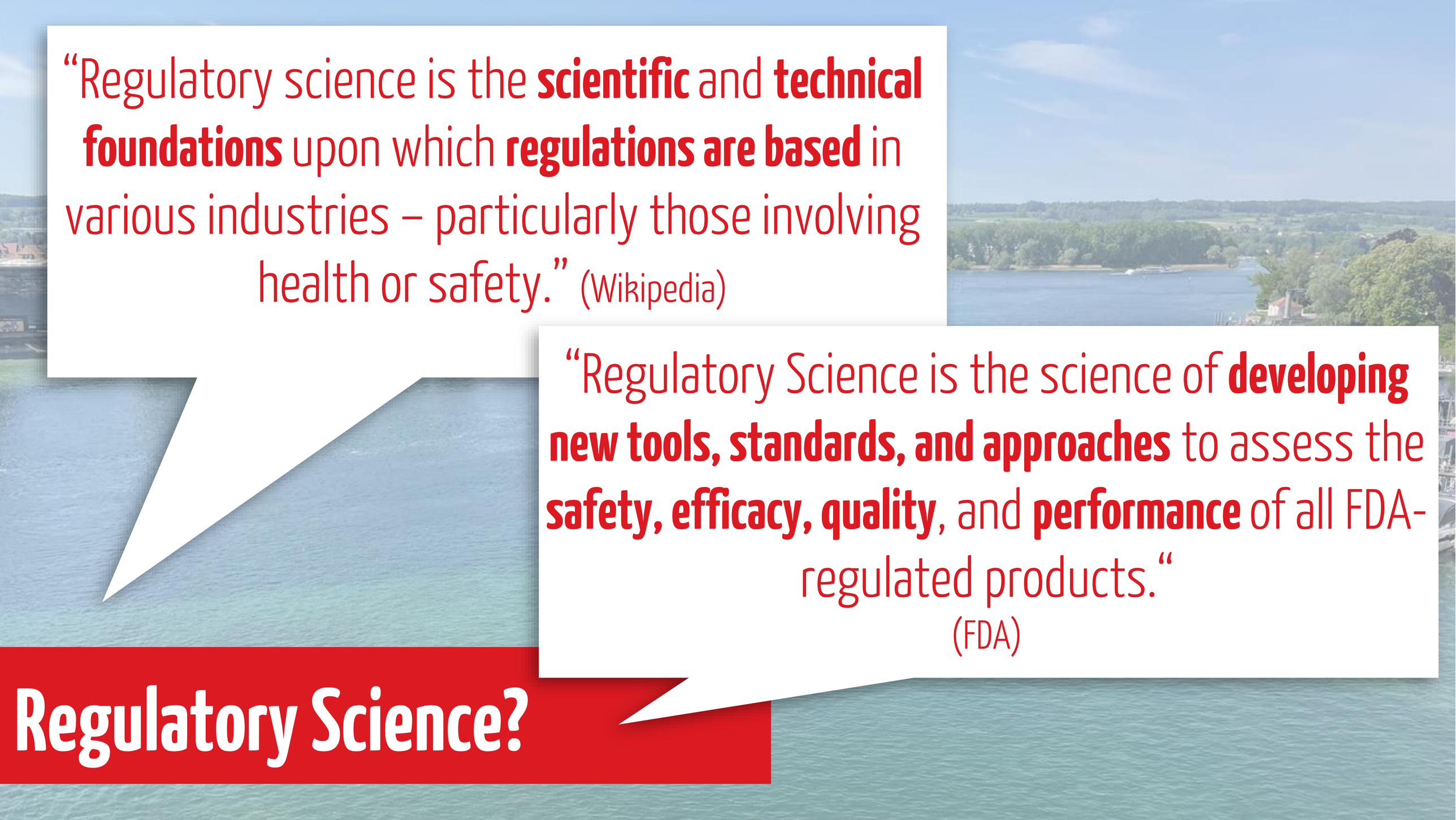
Ziele der Regulierung

- Gute Regulierung?
- Patientensicherheit
- Verfügbarkeit der Produkte
- Förderung der Innovation

WMDS 2023

Charakteristiken guter Regulierung

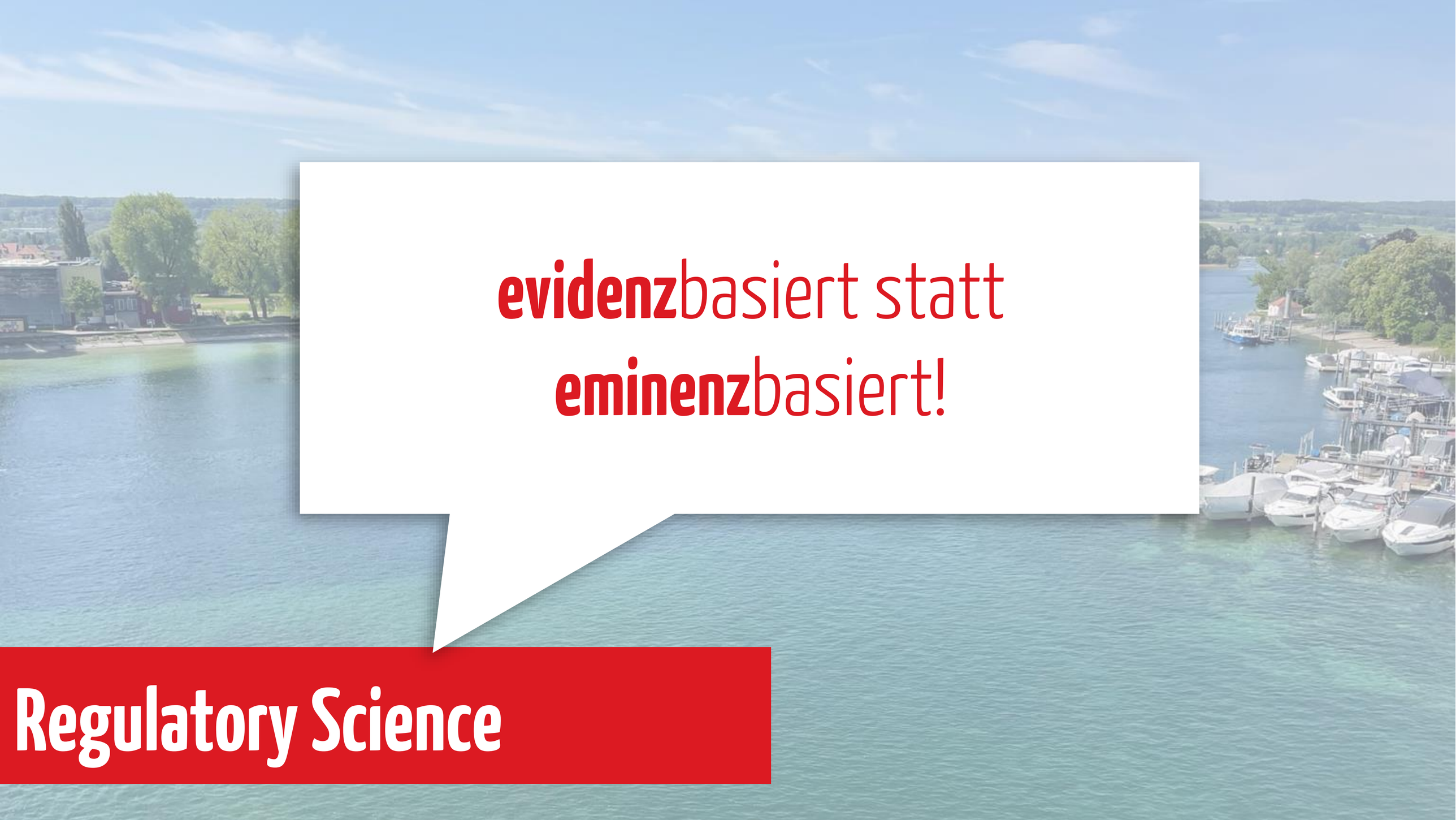
- Regulatorische Vorgaben
  - Verständlichkeit
  - Inhaltliche und formale Korrektheit
  - Innere Konsistenz
  - Umsetzbarkeit
  - …
- Prozess zum Schaffen regulatorischer Vorgaben



"Regulatory science is the **scientific** and **technical foundations** upon which **regulations are based** in various industries – particularly those involving health or safety." (Wikipedia)

"Regulatory Science is the science of **developing new tools, standards, and approaches** to assess the **safety, efficacy, quality**, and **performance** of all FDA-regulated products."
(FDA)

Regulatory Science?


evidenzbasiert statt
eminenzbasiert!
Regulatory Science

Unser Ziel – Verbesserung des regulatorischen Systems

1. Klarheit über den **Status Quo** erreichen (anhand konkreter Kennzahlen)
2. **Voraussagen** über die Zukunft treffen, wenn sich nichts ändert
3. Den Einfluss regulatorischer Änderungen **vorhersagen**

Datenquellen?

"EUDAMED will provide a **living picture** of the lifecycle of medical devices that are made available in the European Union (EU). […]. In doing so, EUDAMED aims to **enhance overall transparency**, including through better **access to information** for the public and healthcare professionals, and to enhance **coordination between** the different **Member States** in the EU."

EUDAMED

EUDAMED wird **nicht geeignet** sein, um die Zielerreichung der MDR zu überprüfen.

EUDAMED

…lementation of EUDAMED?

…. In particular:

…er 2020

…tober 2021

…since October 2021 except for the …ion procedure (CECP)

…erformance Studies and Market Surveillance) are und… …ll be released when EUDAMED is declared fully functional.

In accordance with the transitional provis…ns set out in the medical devices regulations, the mandatory use of the system will start 6 months after the entire EUDAMED system (including all 6 modules) has been declared fully functional following an independent audit, and the publication of a Commission notice in the Official Journal of the European Union.

data.europa.eu enthält Daten, diese sind allerdings **nicht einheitlich** strukturiert und bei weitem **nicht vollständig**.

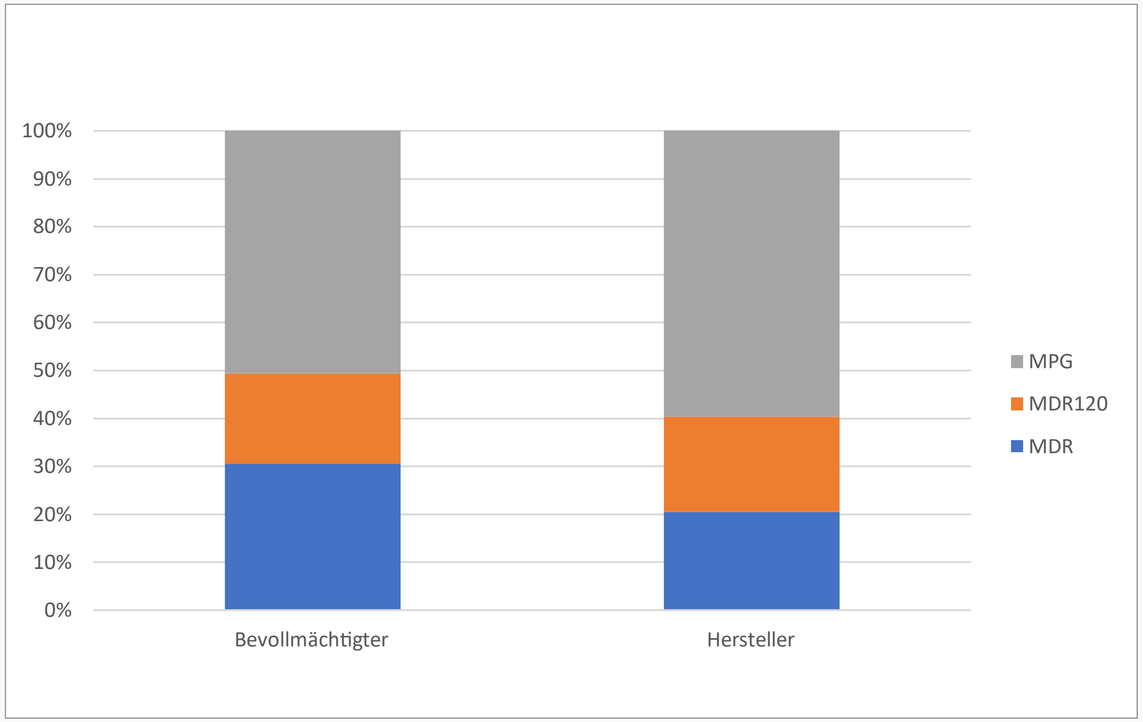
data.europa.eu

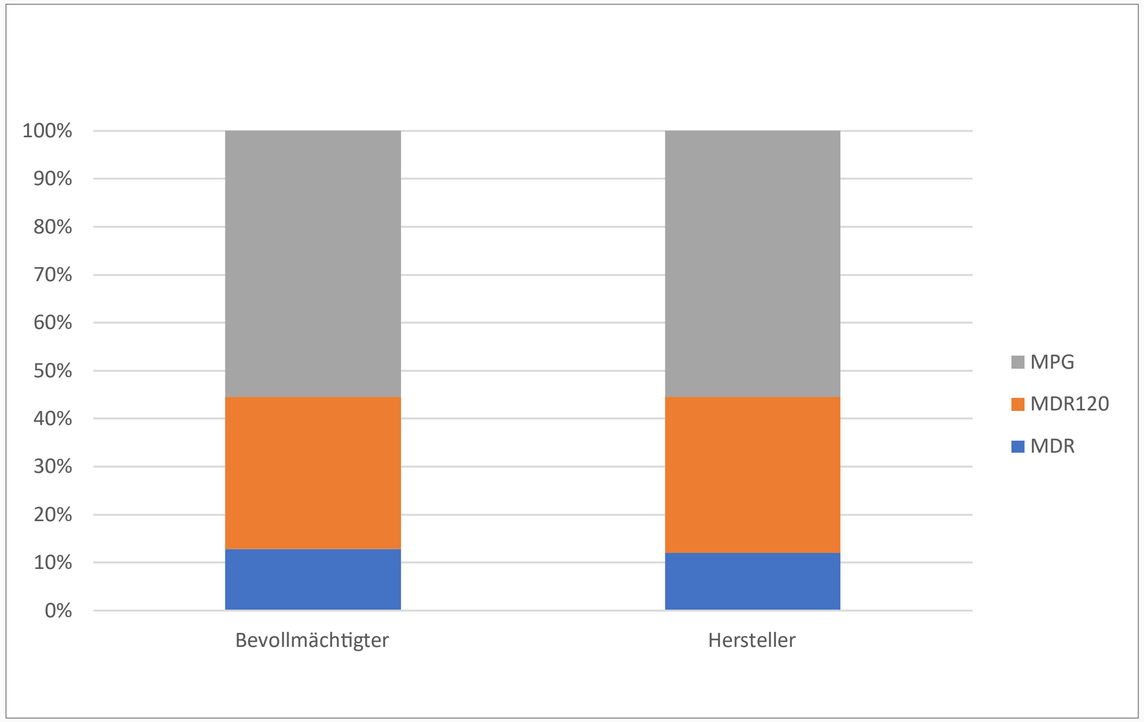
Nationale Datenbanken


Bundesinstitut
für Arzneimittel
und Medizinprodukte
SUCHE
ENGLISH
PRESSE
KONTAKT
TWITTER
LEICHTE SPRACHE
GEBÄRDENSPRACHE
Arzneimittel
Medizinprodukte
Kodiersysteme
Bundesopiumstelle
Das BfArM
Aktuelles
DMIDS
Deutsches Medizinprodukte-Informations- und Datenbanksystem

DMIDS

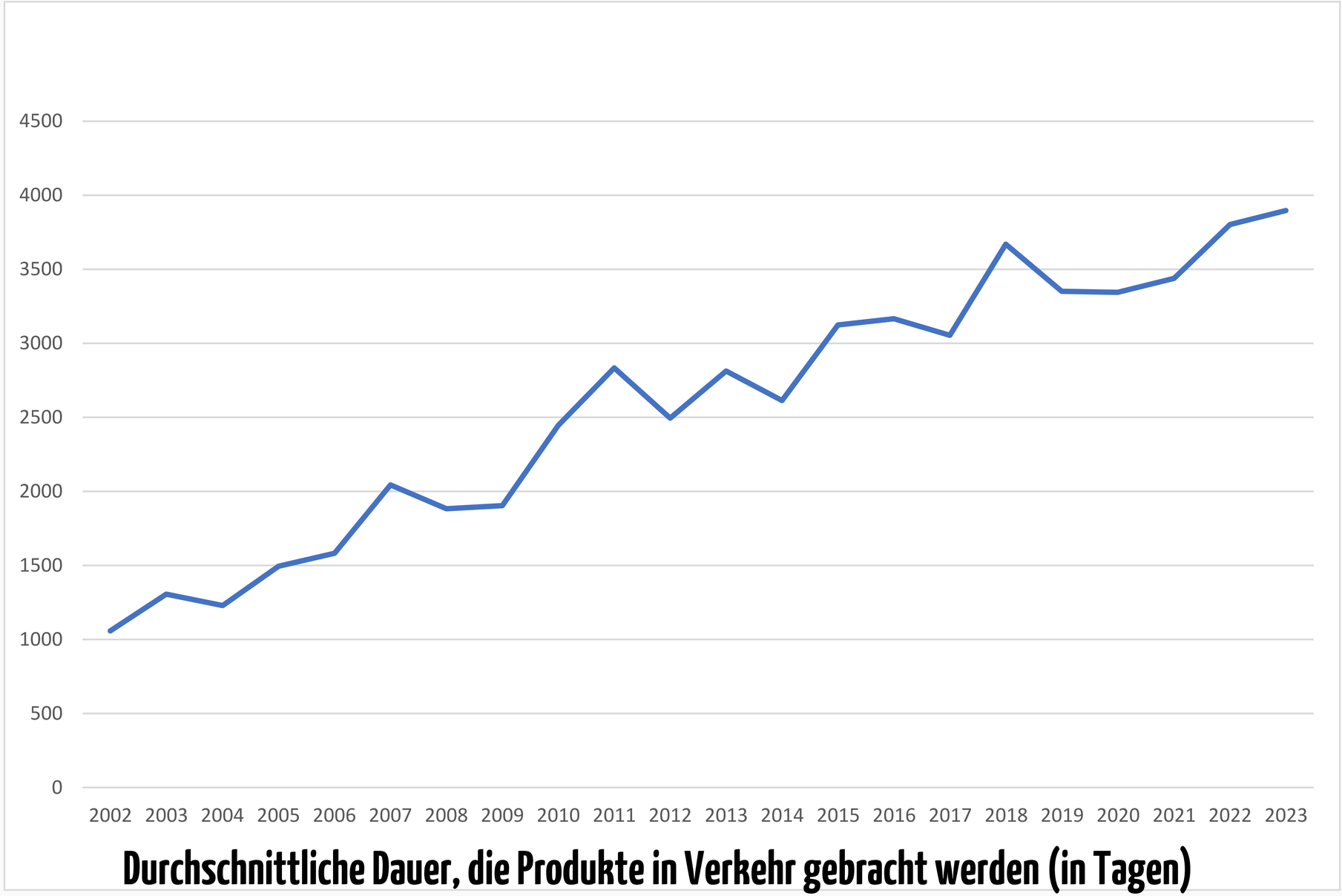
80-90% der derzeit im Markt befindlichen Produkte sind “tot”



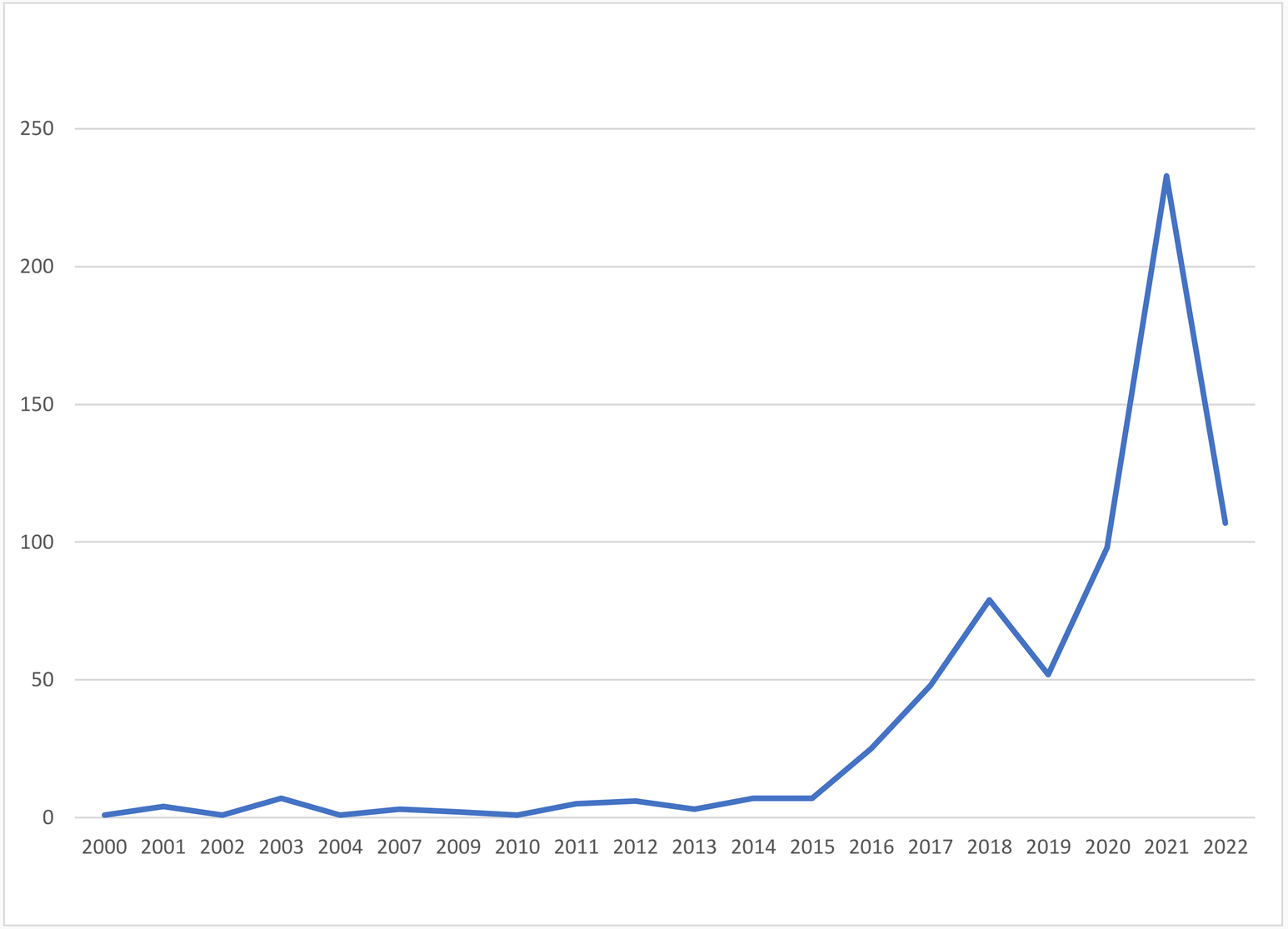


Rechtsgrundlage, unter denen die Produkte derzeit im Markt sind (links: alle, rechts: Klasse>I)

Die Dauer, die Produkte in Verkehr gebracht werden, steigt

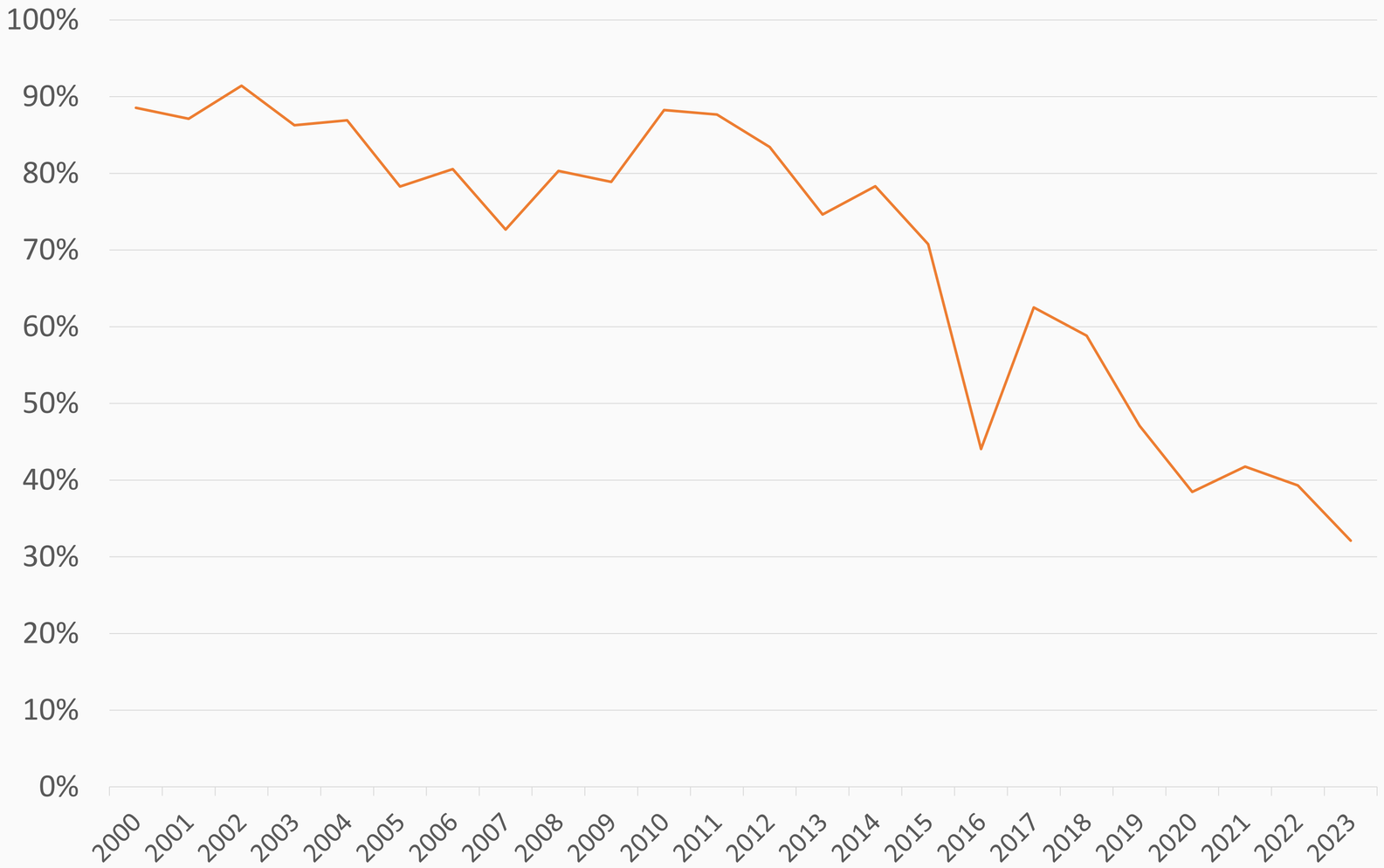


Innovationen wurden durch die MDR ausgebremst



Anzahl der erstangezeigten Medical Apps pro Jahr

Deutsche Hersteller verlieren signifikant an Marktanteilen



Anteil der durch deutsche Hersteller über Deutschland für den europäischen Markt erstangezeigten Produkte

Die Datenbank enthält z.T. kritische Fehler

Produkte wurden fälschlich unter MDR angezeigt.

Nichtaktives Einmal-produkt wurde als Medical App gekennzeichnet

- ✓ Für die Evaluierung der MDR werden **S.M.A.R.T.e Ziele** benötigt.
- ✓ Die Erreichung der Ziele muss mit **Kennzahlen** prüfbar sein.
- ✓ Es existieren nur **wenige Daten(banken)**, die zur Erhebung der Kennzahlen herangezogen werden können.
- ✓ Die obigen Punkte sind Aufgaben der **Regulatory Science**.
- ✓ Regulatory Science muss mehr **gefördert** und – unabhägig – finanziell unterstützt werden.

Zusammenfassung

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- **MEDICA**, Düsseldorf, 13.-16. November 2023
- **MedConf**, München, 16.-18. April 2024