...making excellence a habit.™

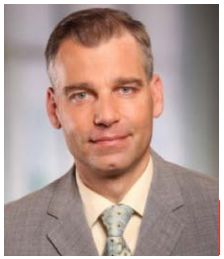
MDD vs. MDR:
Herausforderungen für Medizinprodukteheersteller

7. November 2017

Wien

BSI, a Royal Charter Company

Vortragender

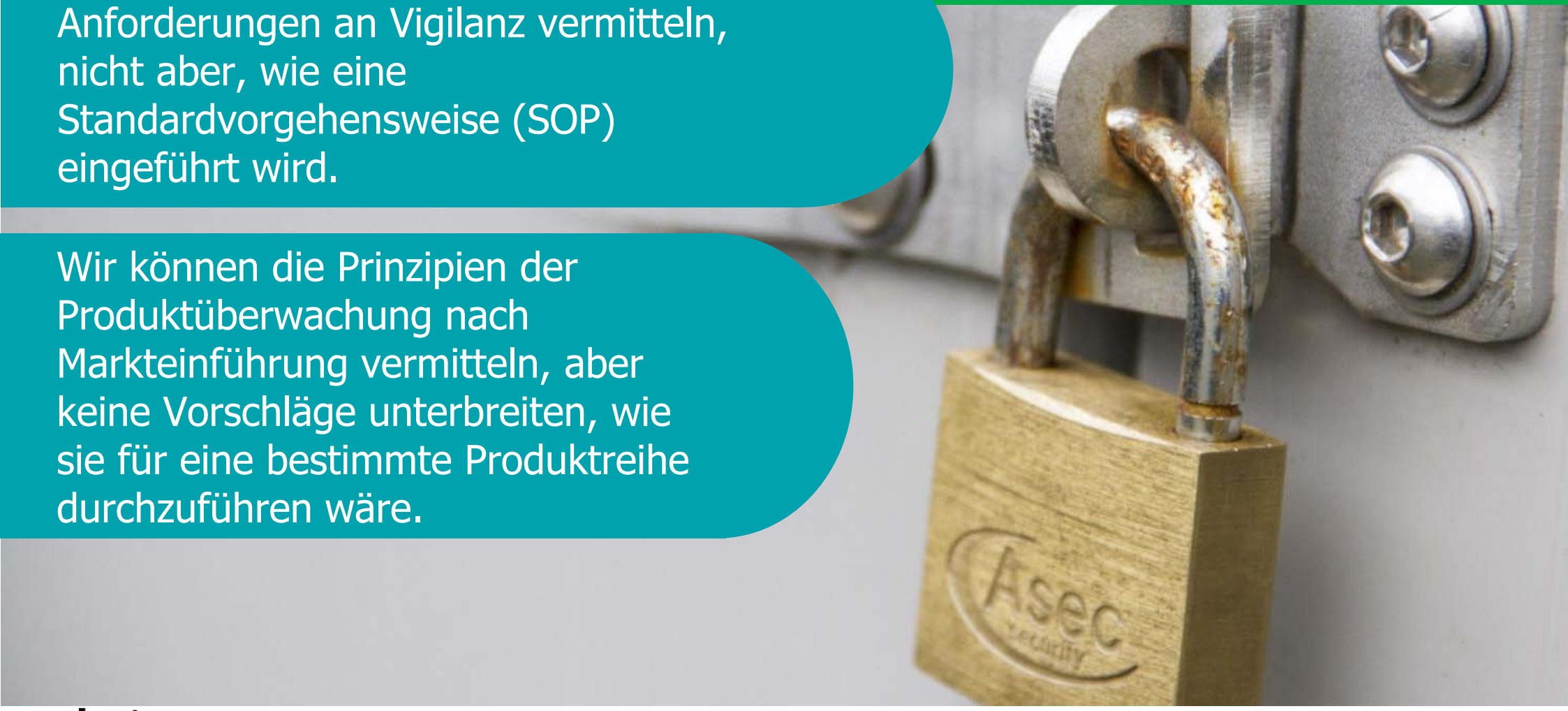


- Dr. Marco Rost
- Trainer –
  Medical Devices

Grenzen: Konflikt von Interesse und Expertise

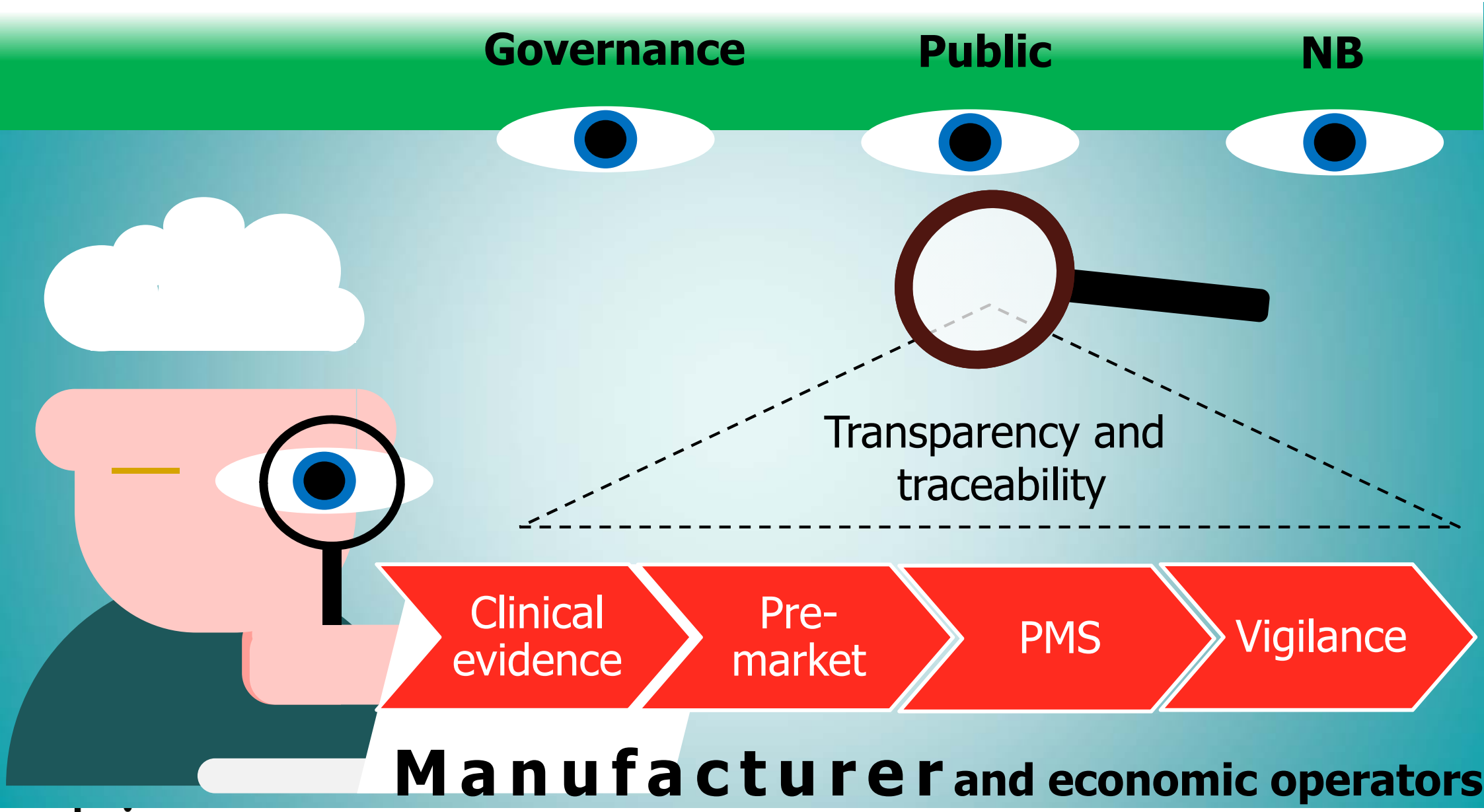
Wir können die behördlichen Anforderungen an Vigilanz vermitteln, nicht aber, wie eine Standardvorgehensweise (SOP) eingeführt wird.

Wir können die Prinzipien der Produktüberwachung nach Markteinführung vermitteln, aber keine Vorschläge unterbreiten, wie sie für eine bestimmte Produktreihe durchzuführen wäre.



Key Changes …

The magnifying glass



Key changes

Notified Bodies	• Strengthened Designation Criteria • Joint Audits: Three Member States and Commission (FHAA) • Unannounced audits
Clinical Evidence	• Less Equivalence, More Data for High Risk Devices • Publish Safety and Performance Data • Post Market Clinical Follow-up
Pre-market	• Conformity Assessment • Scrutiny for High Risk Devices

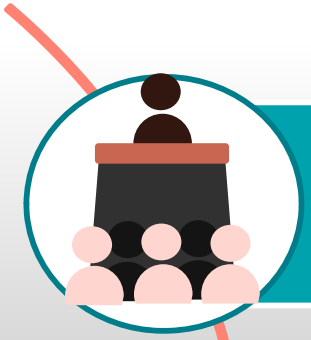
bsi.

Key changes

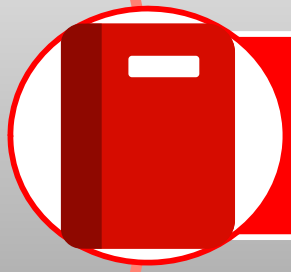
Post-Market Surveillance and Vigilance	• Central Database and Co-ordination • PSUR, SSCP • Implementing Acts, Delegated Acts, Common Specifications
Transparency and Traceability	• Unique Device Identification (UDI) • Implant Cards
Governance and Oversight	• Central Committee: MDCG • Expert Panel, Expert Laboratories

bsi.

Zu prüfende Punkte mit der neuen MPV (MDR)



Rollen und Verantwortungen



Aktualisierung des QMS

Neue Zertifikate

Wie liest man 175 Seiten???

Implementing and Delegated Acts

- Many instances of delegated acts and implementing acts necessary to make MDR "operational"
- Unclear when these will be available…

e.g:

- Regulatory status of groups of products
- Common Specifications
- Format of Summary of Safety and Performance
- UDI
- EUDAMED
- List of NBOG codes
- NB designation procedure

…

CE-Kennzeichnung nach MPV (MDR)

1. Prüfen, ob das Produkt unter die MPV (MDR) fällt	(Kapitel I, §§ 1, 2, Anhang XVI)
2. Risikoklasse des MP feststellen	(Kapitel V, § 51, Anhang VIII)
3. Konformitätsbewertungsverfahren wählen	(Kapitel V, § 52)
4. Anwendbare Sicherheits- und Leistungsanforderungen identifizieren	(Kapitel II, § 5, Anhang I)
5. Technische Dokumentation zusammenstellen	(Anhang I => Anhang II, Anhang XV)
6. Konformitätsbewertungsverfahren durchführen	(Anhänge IX, X, XIA or XIB)
7. endgültige UDI zuteilen	(Kapitel III, § 27, Anhang VI)
8. Konformitätserklärung ausstellen	(Kapitel II, § 19, Anhang IV)
9. CE-Kennzeichen anbringen	(Kapitel II, § 20, Anhang V)
10. Überwachung nach Inverkehrbringen und Aktualisierungen	(Kapitel VII, §§ 83 bis 86, Anhang XIV => Anhang III)

bsi.

Scope of MDR:
Medical and other Devices

Article 2 – Medical Device

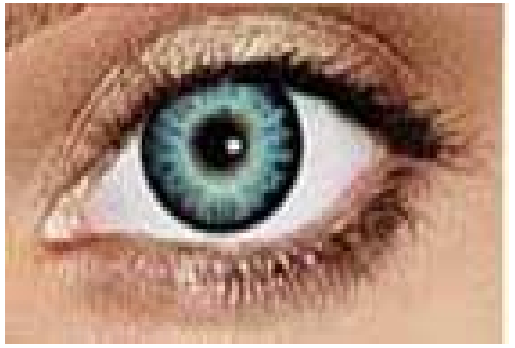
'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- Diagnosis, prevention, monitoring, **prediction, prognosis,** treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or **disability**,
- Investigation, replacement or modification of the anatomy or of a physiological **or pathological** process **or state**,
- **Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations**

Article 1 excludes *IVD* devices from this Regulation

bsi.

Article 1-Scope Annex XVI-No Medical Purpose



Within MDR Scope? ❑ **Yes** ❑ **No**

✓

Scope includes: Contact lenses or other articles intended to be introduced into or onto the eye

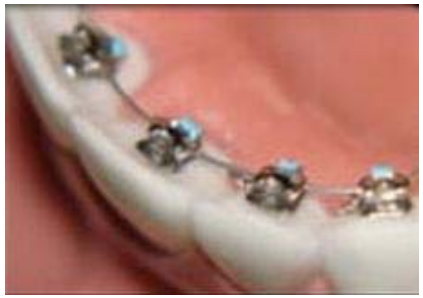
bsi.

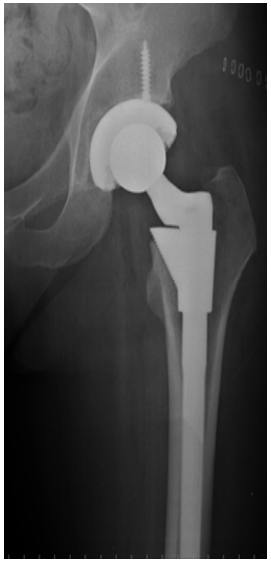
Classification
Annex VIII

22 Classification Rules:

1 - 4 Non invasive devices

5 - 8 Invasive devices





9 - 13 Active devices

14 - 22 Special rules

bsi.

Veränderung von Regeln:

Regel 2

Alle nicht invasiven Produkte für die Durchleitung oder Aufbewahrung von Blut, anderen Körperflüssigkeiten, -zellen oder -geweben, Flüssigkeiten oder Gasen zum Zwecke einer Infusion, Verabreichung oder Einleitung in den Körper gehören

zur Klasse IIa, — wenn sie mit einem aktiven Produkt der Klasse IIa, der Klasse IIb oder der Klasse III verbunden werden können oder — wenn sie für die Durchleitung oder Aufbewahrung von Blut oder anderen Körperflüssigkeiten oder für die Aufbewahrung von Organen, Organteilen oder Körperzellen und -geweben eingesetzt werden,

mit Ausnahme von Blutbeuteln; Blutbeutel gehören zur Klasse IIb.

In allen anderen Fällen gehören solche Produkte zur Klasse I.

Repealed Directives:

- 2003/12/EC
  - Breast implants raised to class III.

- 2005/50/EC
  - Hip, knee and shoulder joint replacements raised to class III.

bsi.

Veränderung von Regeln:

Rule 14

Alle Produkte, zu deren Bestandteilen

- ein Stoff gehört, der für sich allein genommen als Arzneimittel im Sinne des Artikels 1 Nummer 2 der Richtlinie 2001/83/EG gelten kann
- ~~and which is liable to act on the human body (der auf den menschlichen Körper einwirken kann)~~
- auch wenn es sich um ein Arzneimittel aus menschlichem Blut oder Blutplasma im Sinne des Artikels 1 Nummer 10 der genannten Richtlinie handelt
- und dem im Rahmen des Medizinprodukts eine unterstützende Funktion zukommt,

werden der Klasse III zugeordnet.

Veränderung von Regeln:

Regel 17

Alle Produkte, die unter Verwendung

- von nicht lebensfähigen oder abgetöteten Geweben oder Zellen
- menschlichen oder tierischen Ursprungs oder ihren Derivaten hergestellt wurden,

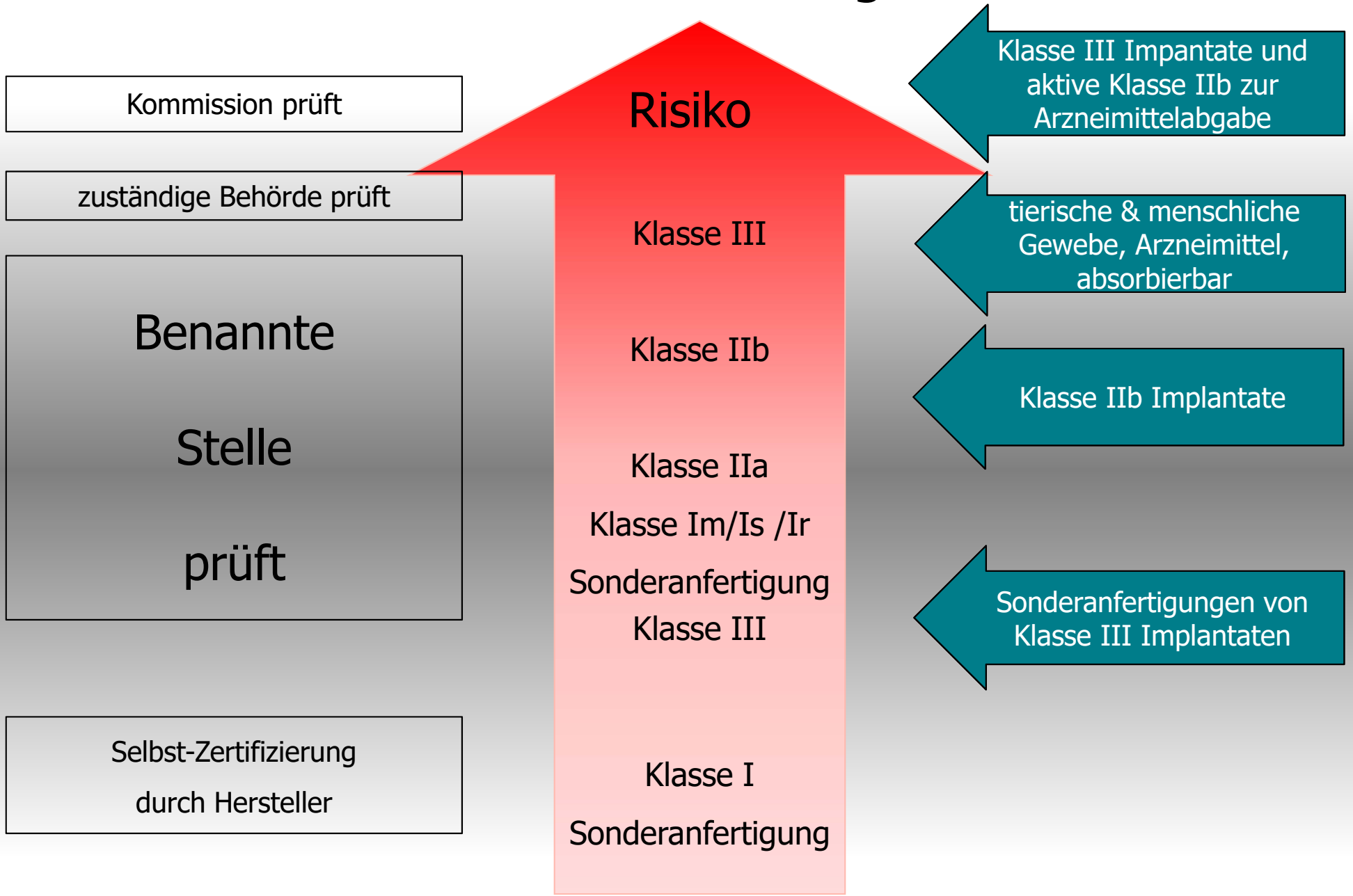
werden der Klasse III zugeordnet,

- es sei denn, diese Produkte werden unter Verwendung von nicht lebensfähigen oder abgetöteten Geweben oder Zellen tierischen Ursprungs oder ihren Derivaten hergestellt, die dafür bestimmt sind, nur mit unversehrter Haut in Berührung zu kommen.

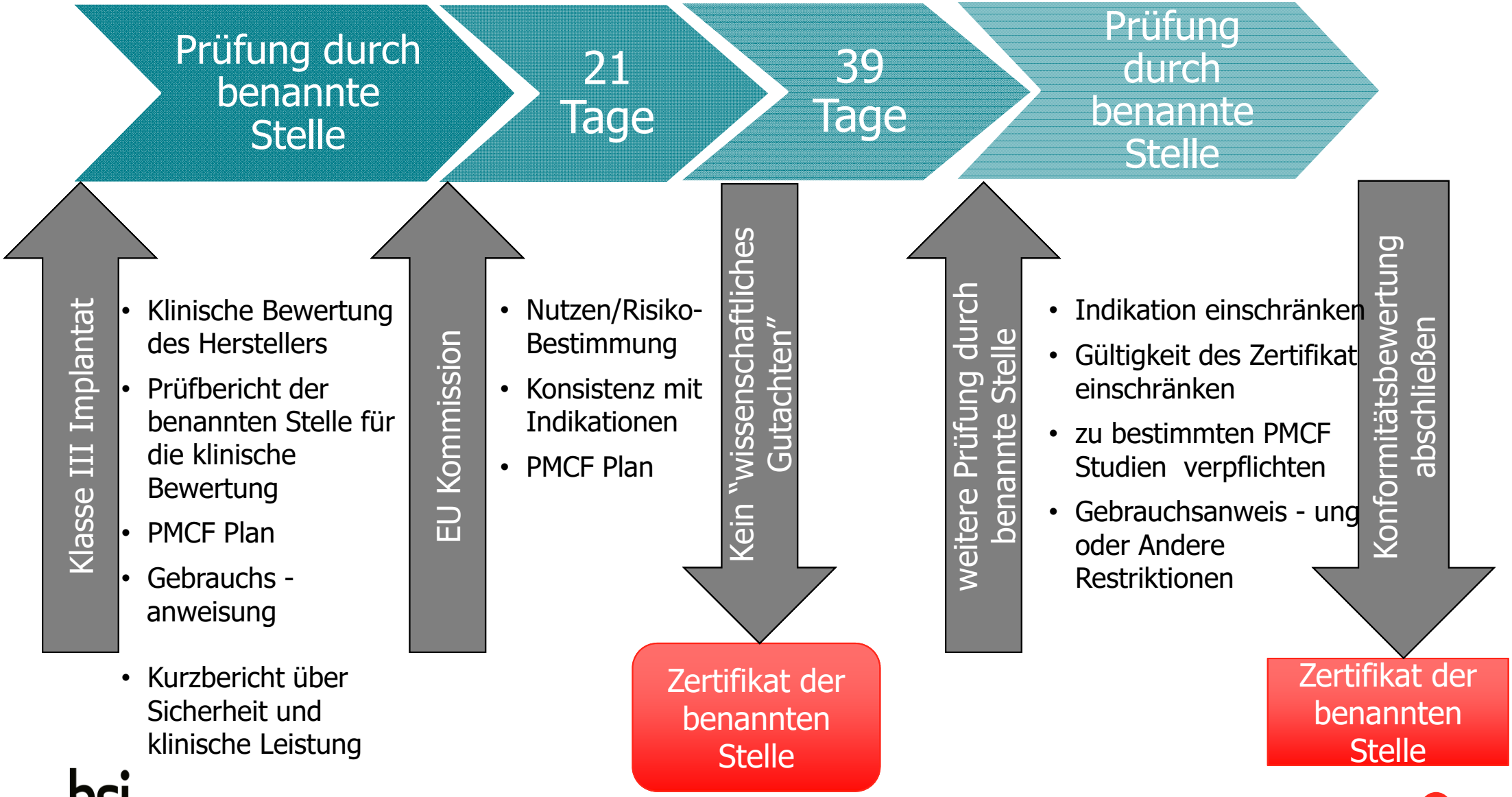
bsi.

Conformity Assessment Procedures

Kontrollen in der Konformitätsbewertung



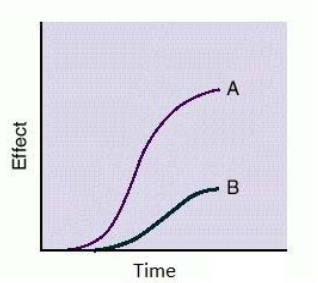
Verfahren für ein Klasse-III-Implantat (Scrutiny)



Annex I: Safety & Performance Requirements

Annex I – Safety & Performance Requirements

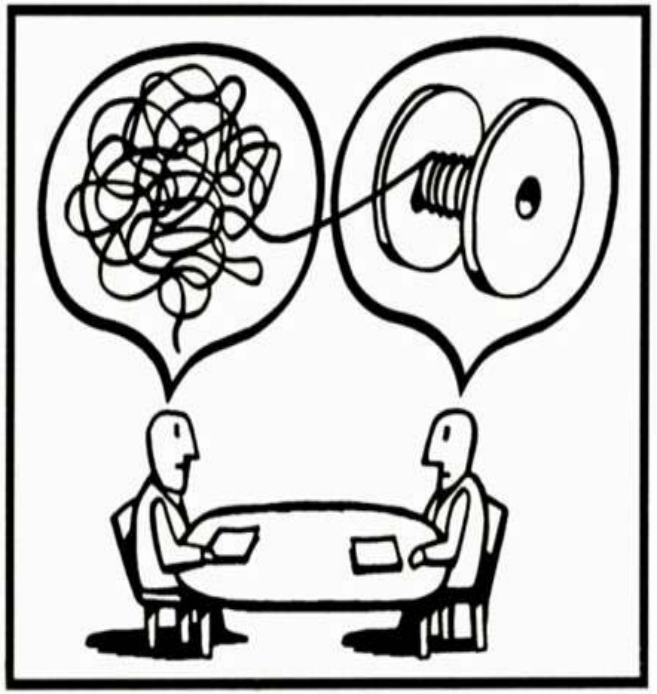
1. Safe, Perform as Intended, State of the Art



Much more emphasis on risk management (summarises risk management process from EN ISO 14971)

Artikel 5

(6) Zur Sicherstellung der einheitlichen Anwendung des Anhangs I kann die Kommission Durchführungsrechtsakte erlassen, soweit dies für die Lösung von Problemen im Zusammenhang mit Unterschieden bei der Auslegung und Problemen der praktischen Anwendung erforderlich ist.



Common Specifications – Article 7

…where:

- no harmonized standards exist or
- where relevant harmonised standards are not sufficient, **or**
- **where there is a need to address public health concerns,**

the Commission **… may** adopt common specifications (**CS**)

Where can these apply?

- the general safety and performance requirements set out in Annex I,
- the technical documentation set out in Annex II and III
- the clinical evaluation and post-market clinical follow-up set out in Annex XIV
- the requirements regarding clinical investigation set out in Annex XV.

BSI Transitions
Medical Devices Regulation

Medical Devices Regulation (MDR)

Mapping Guide

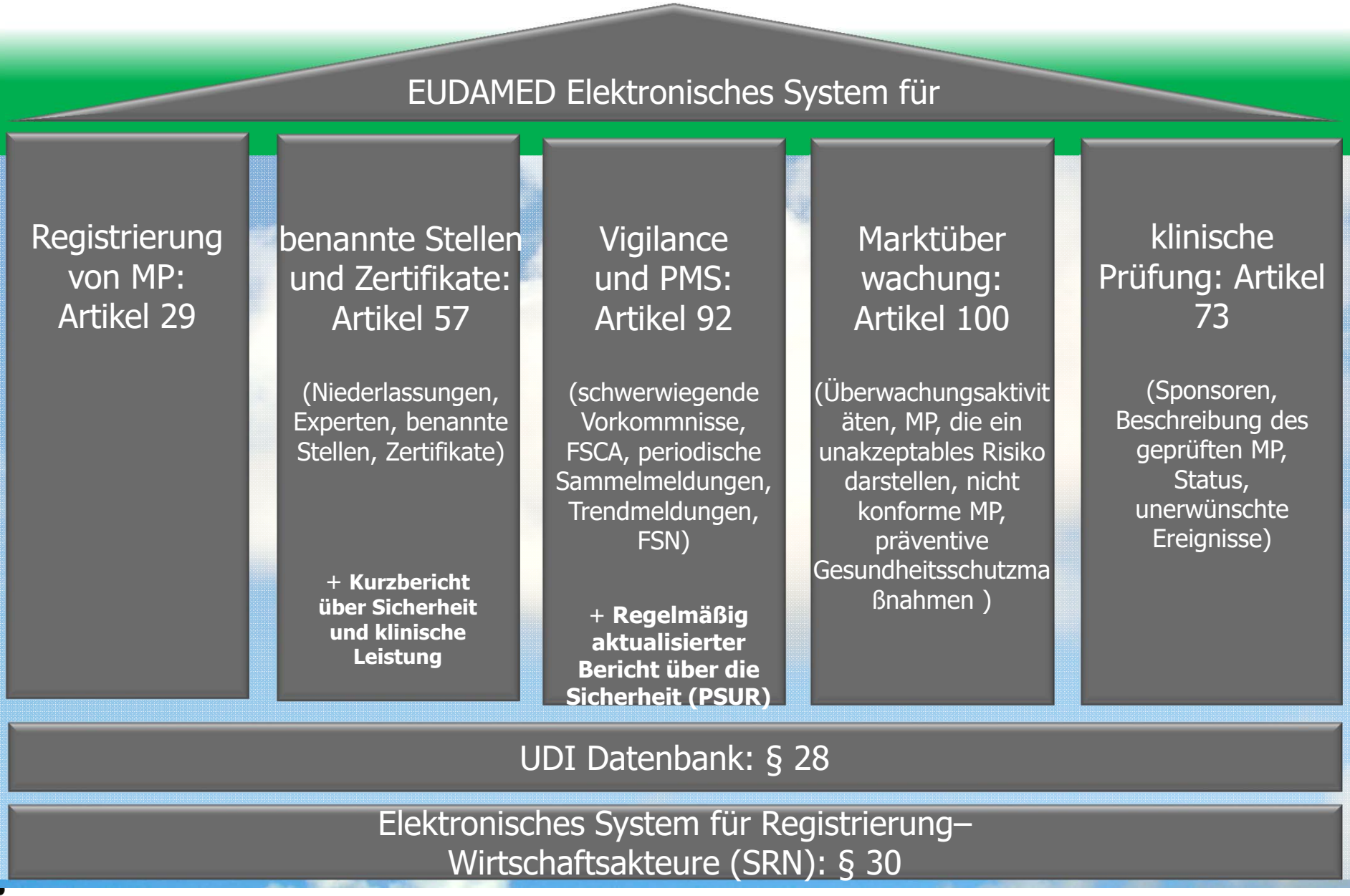
Low priority | Medium priority | High priority

A guide to help you to map the MDR Safety and Performance Requirements (SPRs) to the Essential Requirements for Medical Device Directive (MDD), Active Implantable Medical Device Directive (AIMD). The document also lists other relevant information which can help you in planning your transition to the MDR.

Reference Number			
SPR	MDD	AIMDD	Other
1	1, 2, 3	1, 2,6	-
2	2	8	-
3	-	-	EN ISO 14971
4	2	6	-
5	1	-	-
6	4	3	-
7	5	4	EN ISO 11607-2
8	6	5	-
9	-	-	MDR Annex XVI

Identification and Traceability of Medical Devices

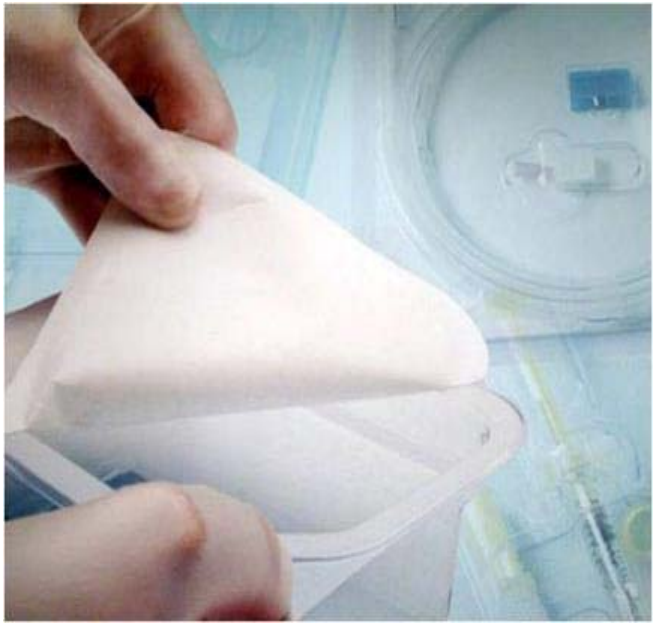
Europäische Datenbank für MP: Artikel 33



Unique Device Identifiers:

Article 27

4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.



Technical Documentation Annex II

Technical Documentation – Annex II

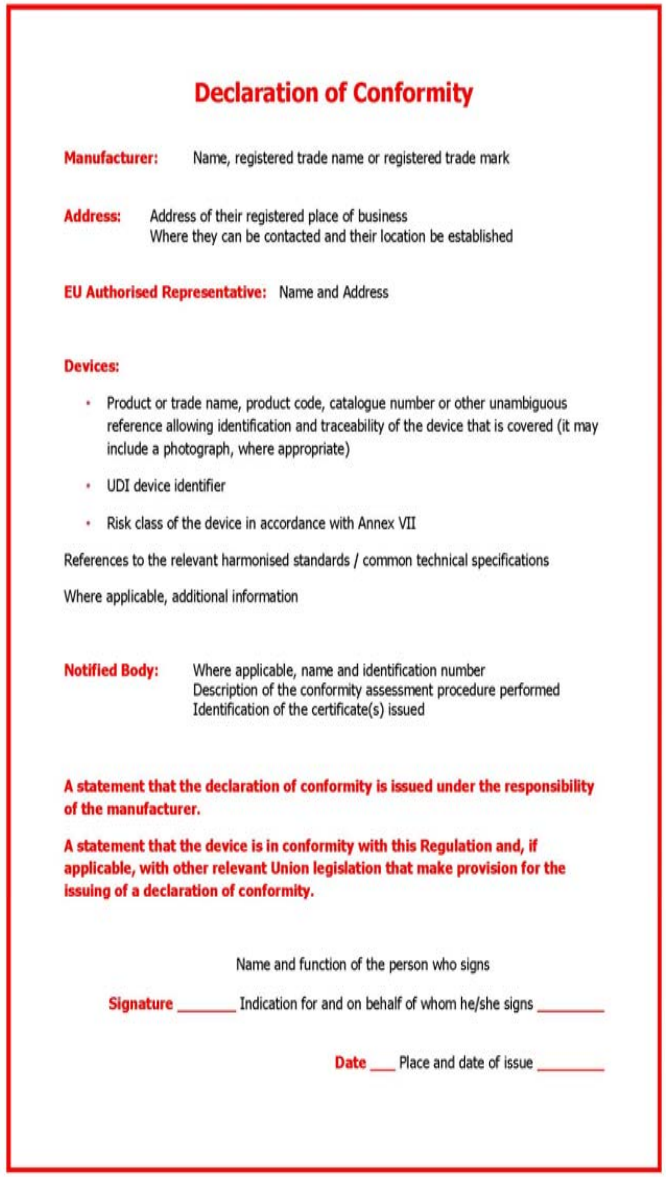
The technical documentation and, if applicable, the (STED) to be drawn up by the manufacturer shall include:

1. DEVICE DESCRIPTION, SPECIFICATION, VARIANTS & ACCESSORIES
   - Device description and specification
   - Reference to previous / similar generations of the device
2. INFORMATION SUPPLIED BY THE MANUFACTURER
3. DESIGN AND MANUFACTURING INFORMATION
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT
6. PRODUCT VERIFICATION AND VALIDATION
   - Pre-clinical and clinical data
   - Additional information in specific cases

bsi.

Declaration of Conformity Annex IV

Declaration of Conformity



Declaration of Conformity

Manufacturer: Name, registered trade name or registered trade mark

Address: Address of their registered place of business
Where they can be contacted and their location be established

EU Authorised Representative: Name and Address

Devices:

- Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered (it may include a photograph, where appropriate)
- UDI device identifier
- Risk class of the device in accordance with Annex VII

References to the relevant harmonised standards / common technical specifications

Where applicable, additional information

Notified Body: Where applicable, name and identification number
Description of the conformity assessment procedure performed
Identification of the certificate(s) issued

A statement that the declaration of conformity is issued under the responsibility of the manufacturer.

A statement that the device is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity.

Name and function of the person who signs

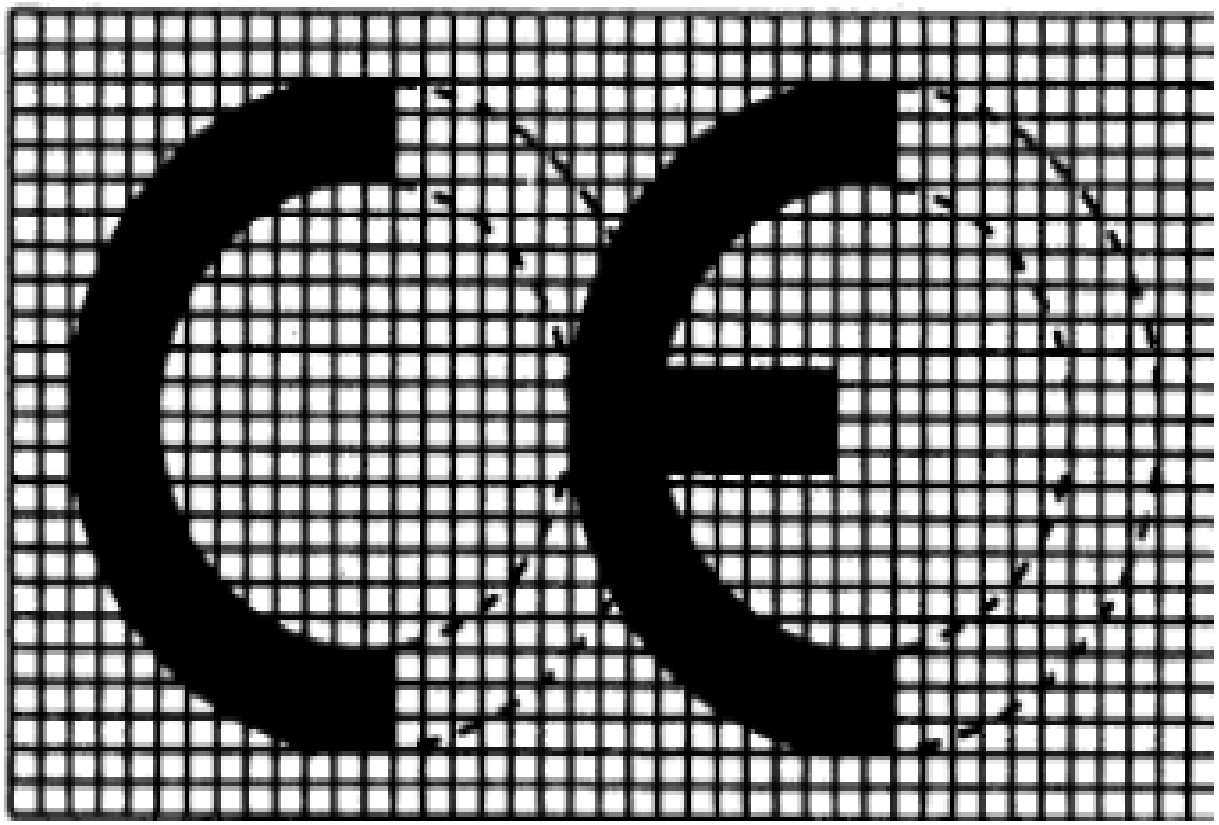
Signature _____ Indication for and on behalf of whom he/she signs _____

Date ___ Place and date of issue _____

- Name, Single Registration Number and address of the manufacturer;
- If applicable, name and address of the authorised representative;
- A statement that the declaration of conformity is issued under the responsibility of the manufacturer;
- UDI
- Product and trade name, product code, catalogue number or other unambiguous reference, including intended purpose;
- Risk class of the device;
- A statement that the device is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;
- References to the relevant harmonised standards / common specifications used in relation to which conformity is declared;
- Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;
- Where applicable, additional information;
- Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.

bsi.

CE Mark
Annex V



Post Market

True or False?

Existing devices will be automatically grandfathered into the new Regulation without need for clinical investigation or further documentation.

❑ **True** ✓❑ **False**

QMS

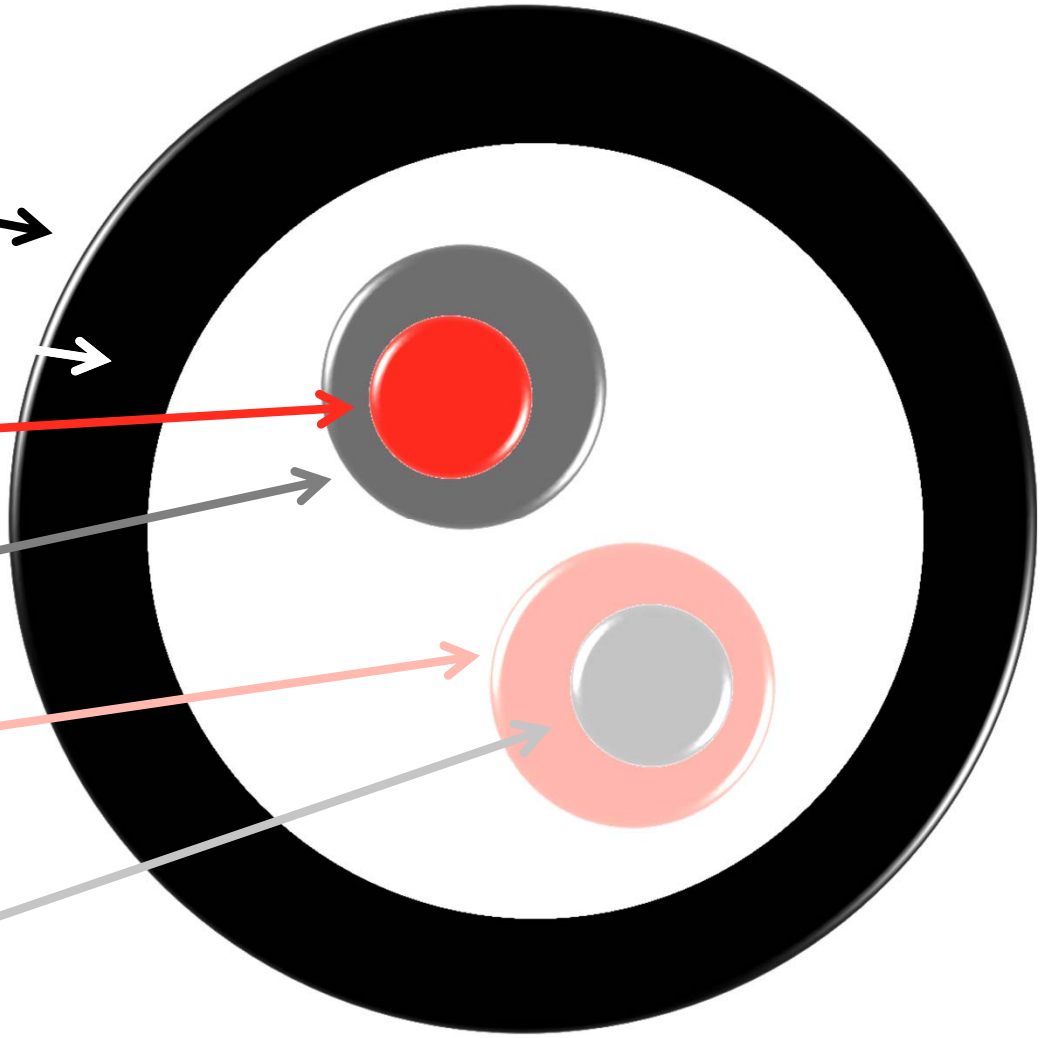
PMS

Vigilance

Reactive PMS

Proactive PMS

Post Market Clinical Follow-up



Applies to every class of device under every route of conformity.

bsi.

Next Steps ...

Notified Body Designation – Key Steps

STEP 1

- **NB** prepares Dossier and Applies for Designation under MDR
- **CA** checks & reviews application dossier, if satisfactory prepares preliminary assessment report and submits to EU Commission
- **EU Commission** upon receipt of Application transmits to JAT & MDCG

STEP 2

- **JAT** (minimum 3 experts) reviews application dossier -> Plans and conducts NB on site assessment
- **NB** prepares any CAPA plan & submits to CA
- **CA** assesses NB CAPA plan and prepares final assessment report -> JAT, EU and MDCG
- **JAT** receives and reviews CAPA Plan & provides final opinion to EU Commission, immediately

STEP 3

- **EU Commission** submits opinion to MDCG
- **MDCG** receives NB application and subsequently CA preliminary assessment report
- **MDCG** receives & reviews final opinion and if satisfactory makes recommendation to CA on draft Designation
- **CA** gives consideration to MDCG recommendation

bsi.

Notified Body Designation – Key Steps (2)

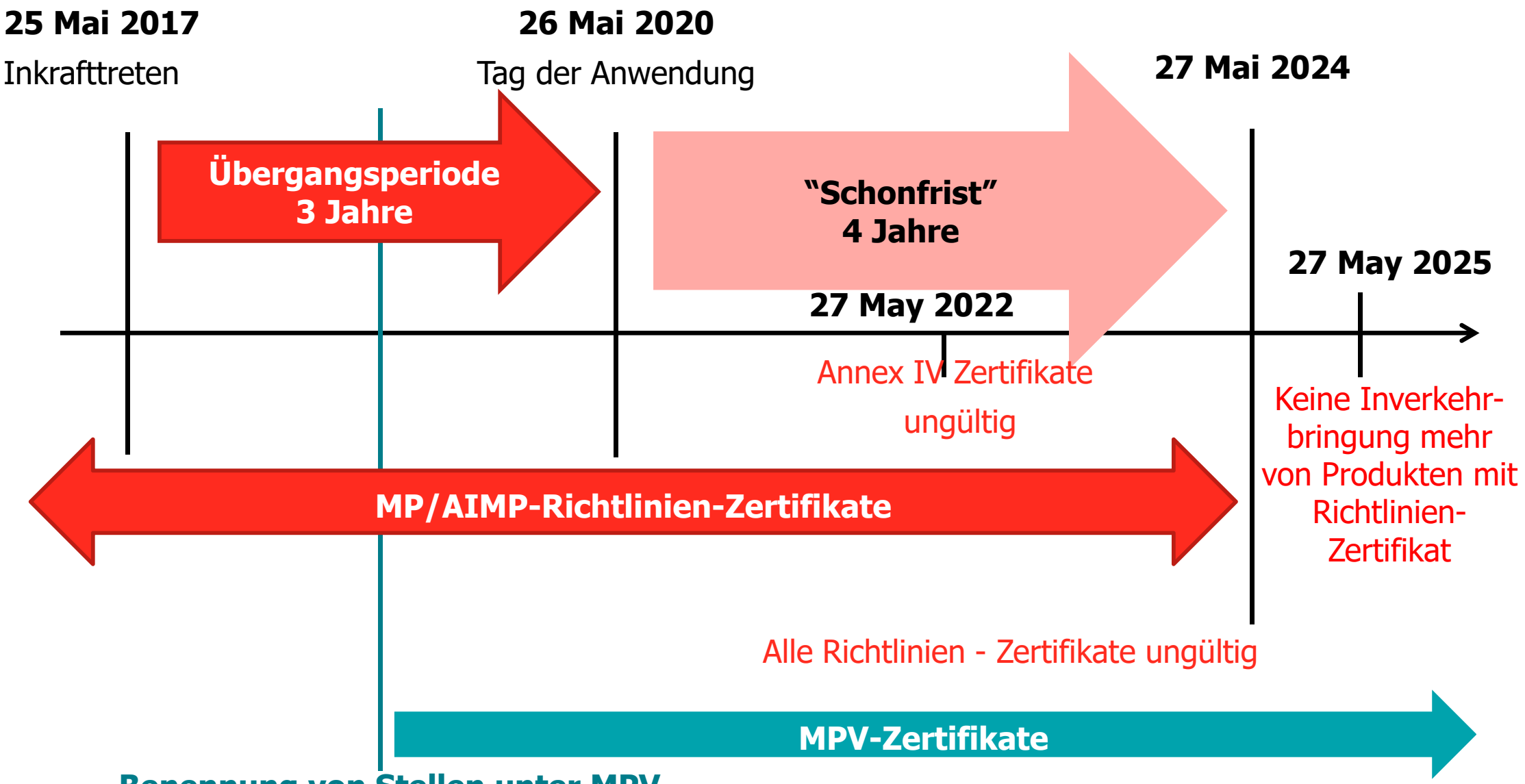
STEP 4

- **CA** designates NB under MDR
- **CA** posts notification decision on EUDAMED
- **EU Commission** publishes notification on NANDO

TOTAL DURATION

- From Start to Finish Approx. 18 Months!

Übergangszeiten für die MPV (§ 120)



Conclusions

- Become familiar with the draft MDR
- Conduct MDR impact assessment on your business
- Plan…..
  - Maintenance of MDD system in your organization
  - Implementation of MDR in your organization
  - Continuously check for changes as Common Specifications, Implementing Acts and Delegated Acts are published
- Hire competent people

bsi.

Danke

und wenn Sie jetzt noch nicht genug haben…

Links:	bsigroup.com/ISO13485revision
LinkedIn:	Please Join our New Global Medical Device LinkedIn Group http://www.linkedin.com/groups/BSI-Global-Medical-Devices

bsi.

...making excellence a habit.™