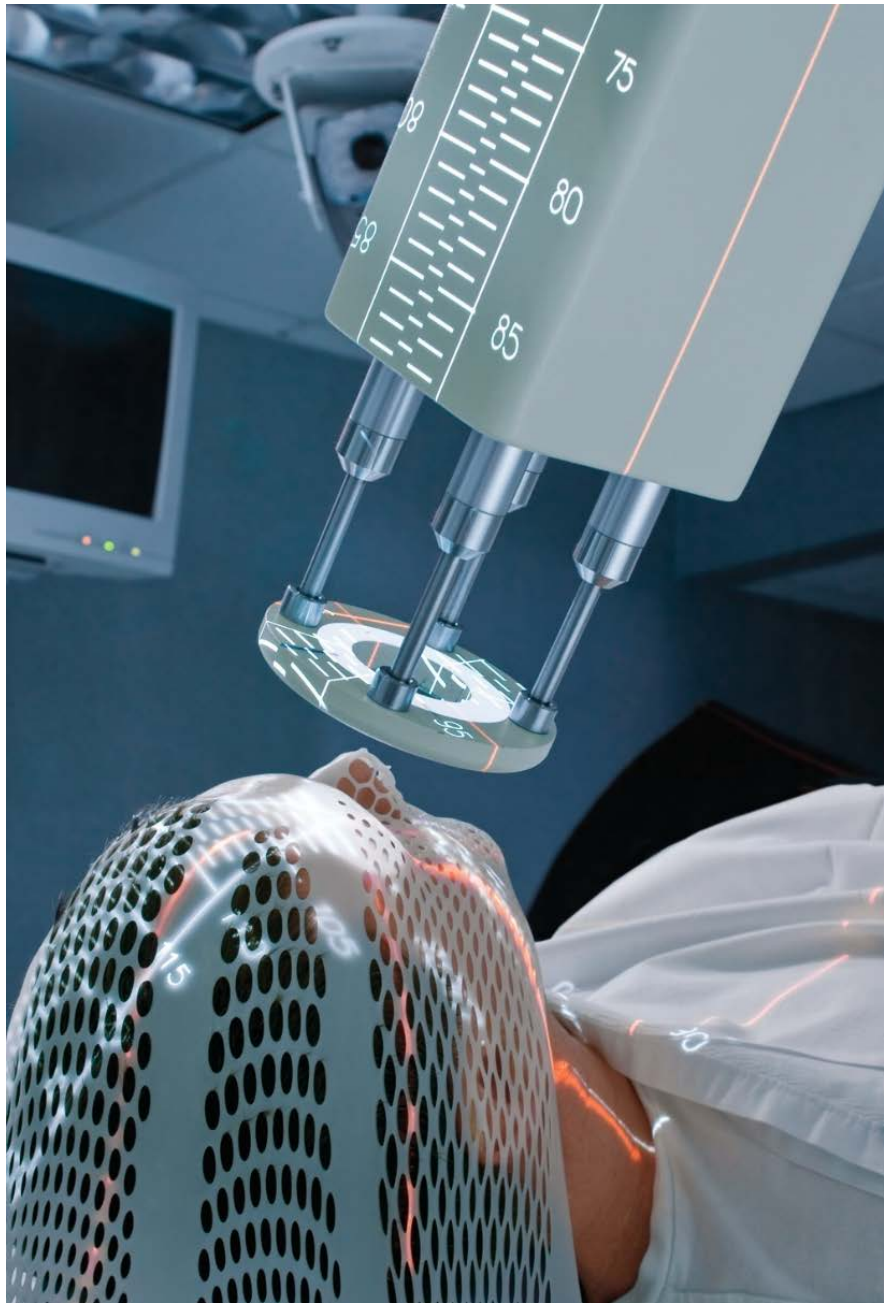


Mehr Wert.
Mehr Vertrauen.

Wien, 12. Oktober 2021

LISAvienna Regulatory Konferenz für Medizinprodukte und In-vitro Diagnostika

Erfahrungen aus den bisherigen MDR-Audits

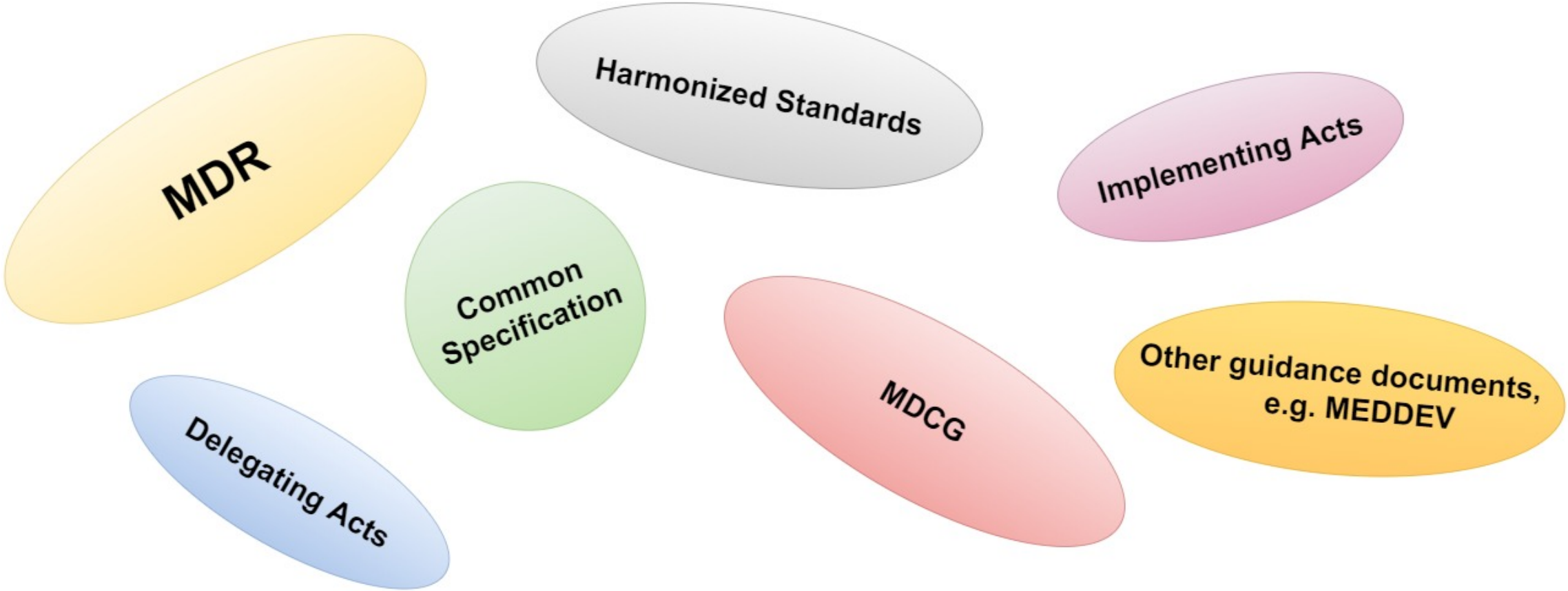
Was meist gut läuft und wo die Fallstricke liegen.
Immer wiederkehrende Schwachstellen im Rahmen von „Technical File Reviews“ und „On Site Audits“

TÜV SÜD Product Service GmbH
Dr. Markus Wagner

Agenda

- Regularien und Guidance Dokumente
- Transition zur MDR
- Generische Probleme
- "On Site Audits"
- TD Bewertung
- Klinische Daten
- Spezielle Nachweise
- Lessons learned

Regularien und Guidance Dokumente



Regularien und Guidance-Dokumente

MDR codes
MDCG 2019-14

Software
MDCG 2019-11

Cybersecurity
MDCG 2019-16

Class I Medical Devices
MDCG 2019-15 Rev. 1

Clinical
MDCG 2020-01, MDCG 2020-05, MDCG 2020-06, MDCG 2020-07, MDCG 2020-08, MDCG 2020-10-1, MDCG 2020-10-2, MDCG 2020-11, MDCG 2020-13

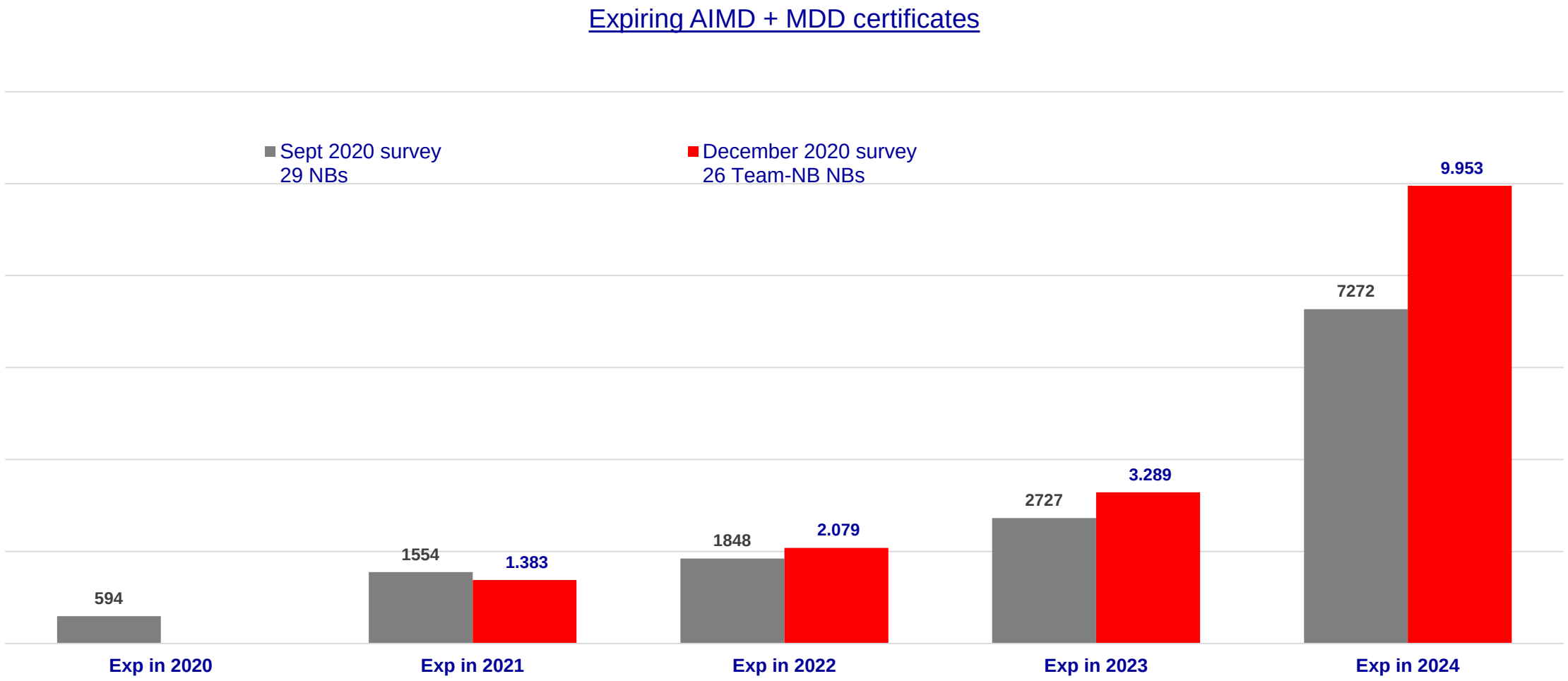
UDI
MDCG 2018-03, MDCG 2018-04, MDCG 2018-05, MDCG 2018-06, MDCG 2018-07, MDCG 2019-01, MDCG 2019-02

Article 120 (Transition period)
MDCG 2020-02, MDCG 2020-03

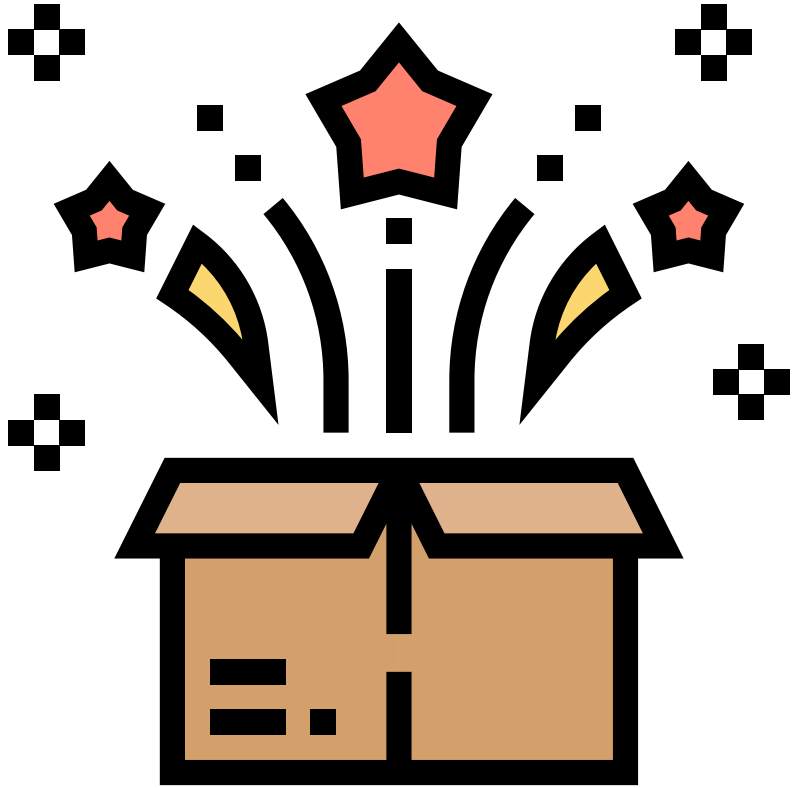
Transition zur MDR

- Kein „Grandfathering“
- Initial Audit Stage 1 + 2
- basiert auf ISO 13485
- Vorteil: ISO 13485 vorhanden
- Stand alone, Kombi RZ, S1, S2

Transition zur MDR



Generische Probleme

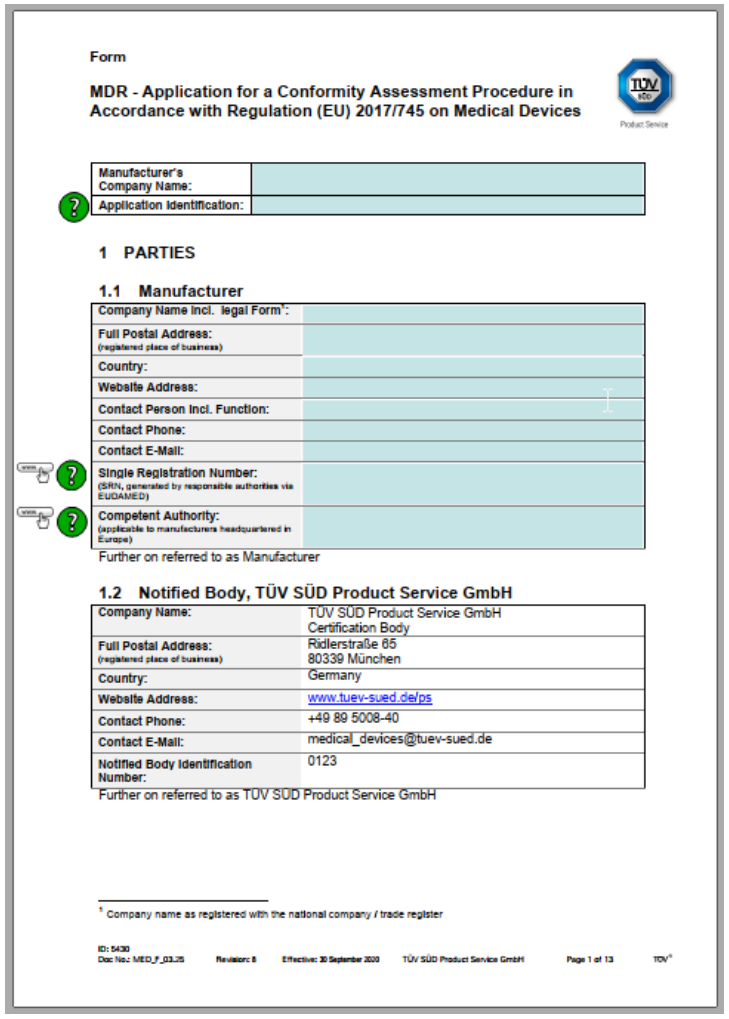


Generische Probleme

Antragsformulare inkonsistent

- Bezeichnungen
- Referenznummer des Antrages
- Scope des Zertifikates nicht passend
- Unterschrift fehlt

Generische Probleme



Form

MDR - Application for a Conformity Assessment Procedure in Accordance with Regulation (EU) 2017/745 on Medical Devices

Manufacturer's Company Name:	
Application Identification:	

1 PARTIES

1.1 Manufacturer

Company Name Incl. legal Form*:	
Full Postal Address: (registered place of business)	
Country:	
Website Address:	
Contact Person Incl. Function:	
Contact Phone:	
Contact E-Mail:	
Single Registration Number: (SRN, generated by responsible authorities via EUDAMED)	
Competent Authority: (applicable to manufacturers headquartered in Europe)	

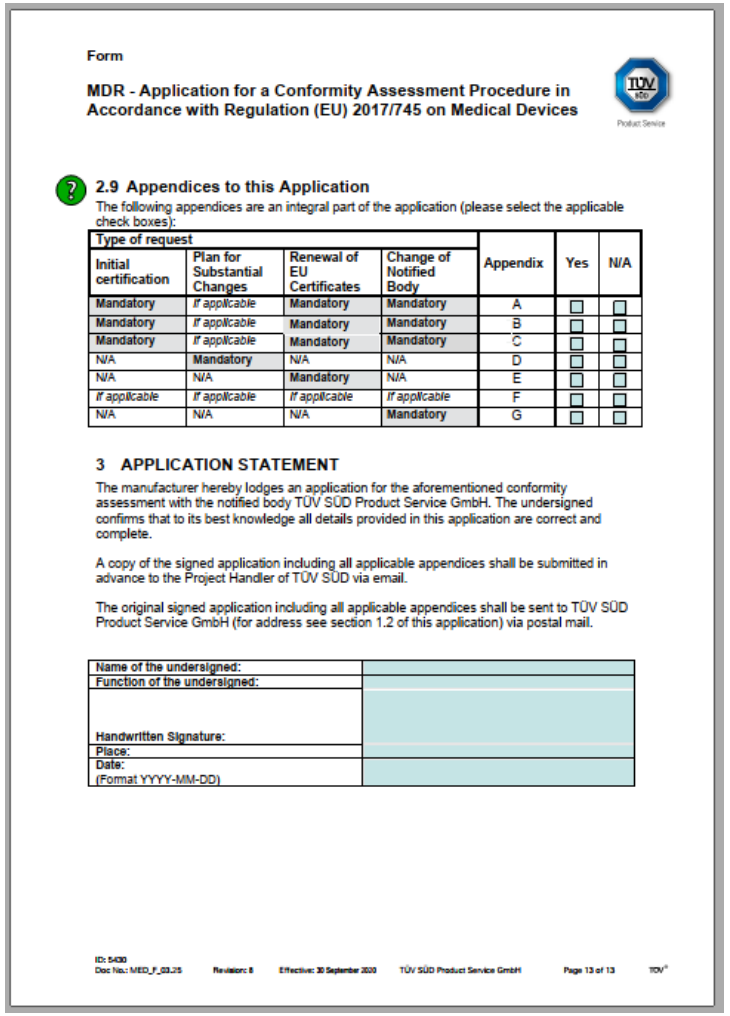
Further on referred to as Manufacturer

1.2 Notified Body, TÜV SÜD Product Service GmbH

Company Name:	TÜV SÜD Product Service GmbH Certification Body
Full Postal Address: (registered place of business)	Ridlerstraße 65 80339 München
Country:	Germany
Website Address:	www.tuev-sued.de/ps
Contact Phone:	+49 89 5008-40
Contact E-Mail:	medical_devices@tuev-sued.de
Notified Body Identification Number:	0123

Further on referred to as TÜV SÜD Product Service GmbH

* Company name as registered with the national company / trade register



Form

MDR - Application for a Conformity Assessment Procedure in Accordance with Regulation (EU) 2017/745 on Medical Devices

2.9 Appendices to this Application

The following appendices are an integral part of the application (please select the applicable check boxes):

Type of request						
Initial certification	Plan for Substantial Changes	Renewal of EU Certificates	Change of Notified Body	Appendix	Yes	N/A
Mandatory	*If applicable*	Mandatory	Mandatory	A	☐	☐
Mandatory	*If applicable*	Mandatory	Mandatory	B	☐	☐
Mandatory	*If applicable*	Mandatory	Mandatory	C	☐	☐
N/A	Mandatory	N/A	N/A	D	☐	☐
N/A	N/A	Mandatory	N/A	E	☐	☐
If applicable	*If applicable*	*If applicable*	*If applicable*	F	☐	☐
N/A	N/A	N/A	Mandatory	G	☐	☐

3 APPLICATION STATEMENT

The manufacturer hereby lodges an application for the aforementioned conformity assessment with the notified body TÜV SÜD Product Service GmbH. The undersigned confirms that to its best knowledge all details provided in this application are correct and complete.

A copy of the signed application including all applicable appendices shall be submitted in advance to the Project Handler of TÜV SÜD via email.

The original signed application including all applicable appendices shall be sent to TÜV SÜD Product Service GmbH (for address see section 1.2 of this application) via postal mail.

Name of the undersigned:	
Function of the undersigned:	
Handwritten Signature:	
Place:	
Date: (Format YYYY-MM-DD)	

Generische Probleme

Intended Purpose problematisch

- Produktnamen sind enthalten
- zu umfangreich, romanhaft
- widersprüchlich
- sollte nahe am CND Code sein

Generische Probleme

CND Codes problematisch

- Gruppe (aktiv, nicht aktiv)
- zu generisch
- MDCG 2020 The CND Nomenclature ‘Classificazione Nazionale Dispositivi medici’
- MDCG 2021-12 FAQ on the European Medical Device Nomenclature (EMDN)

Generische Probleme

Sampling der TD unzureichend:

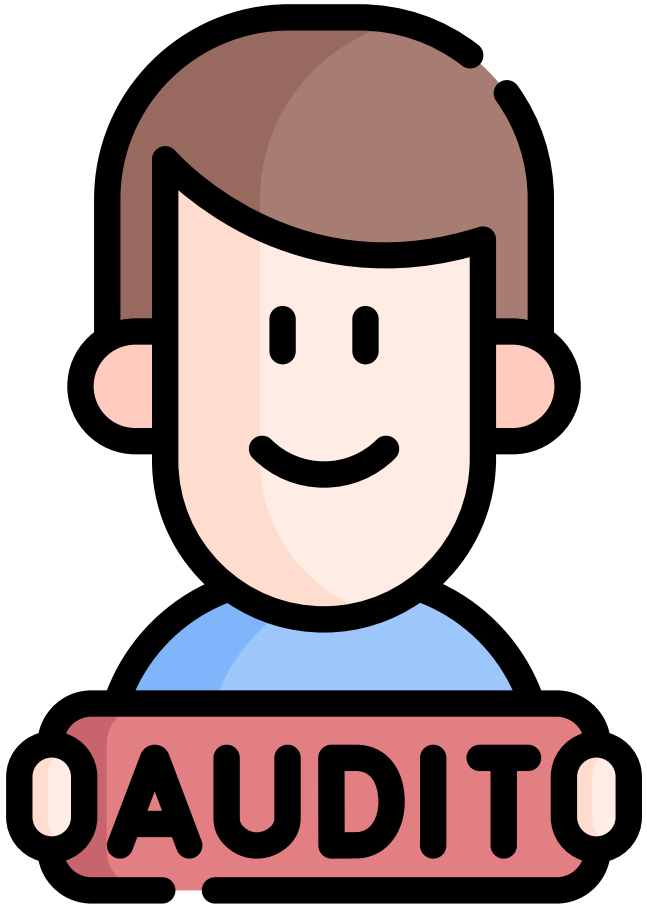
- ein TD pro Produktcode (CND Code) bei Initialaudit
- Accessories vergessen (App, Software)
- Produkt ist ein System ?

Generische Probleme

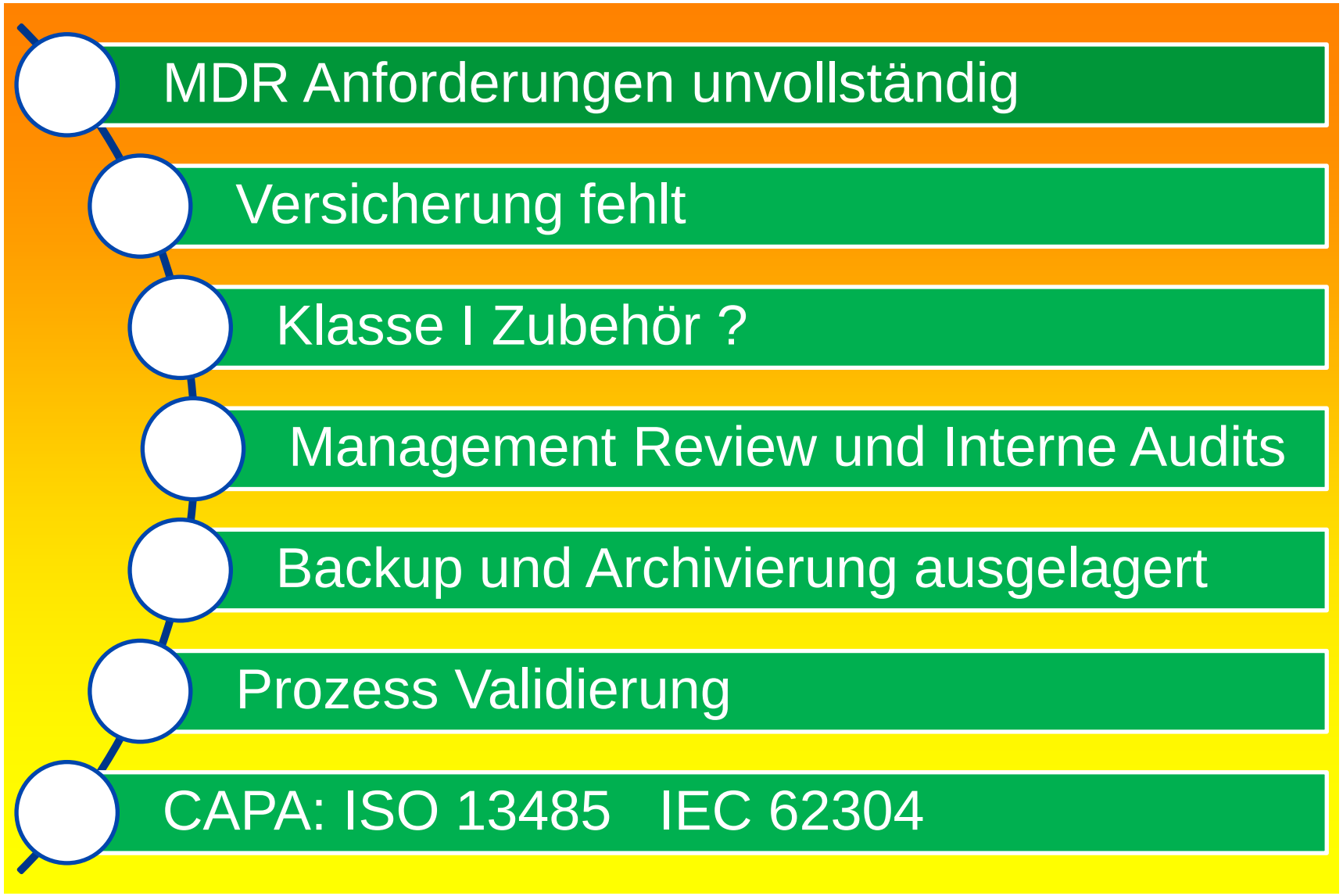
SW Klassifizerung:

- Medizinprodukt / Zubehör
- MDCG 2021: Is your software a medical device
- MDSW, medical intended purpose
- Regel 11: welche Klasse, IMDRF Guide
- MDCG 2019-11 Guidance on Qualification and Classification of Software
- IMDRF "Software as Medical Device": Possible Framework for risk categorization"

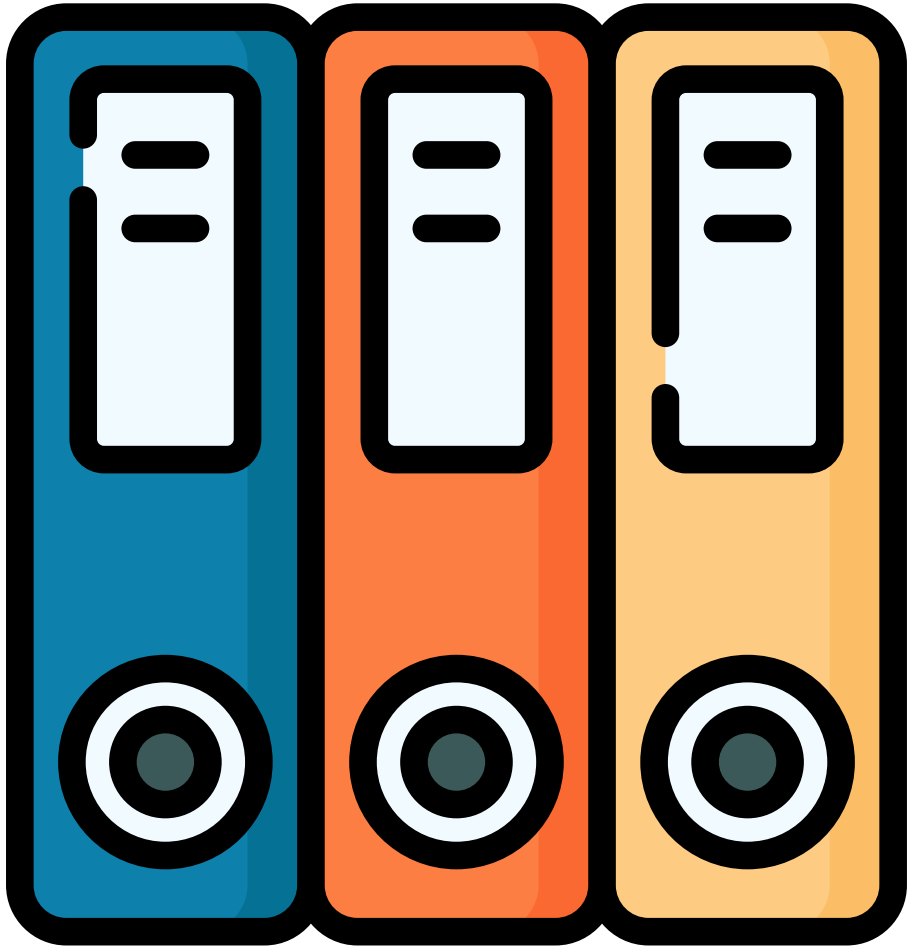
"On Site Audits"



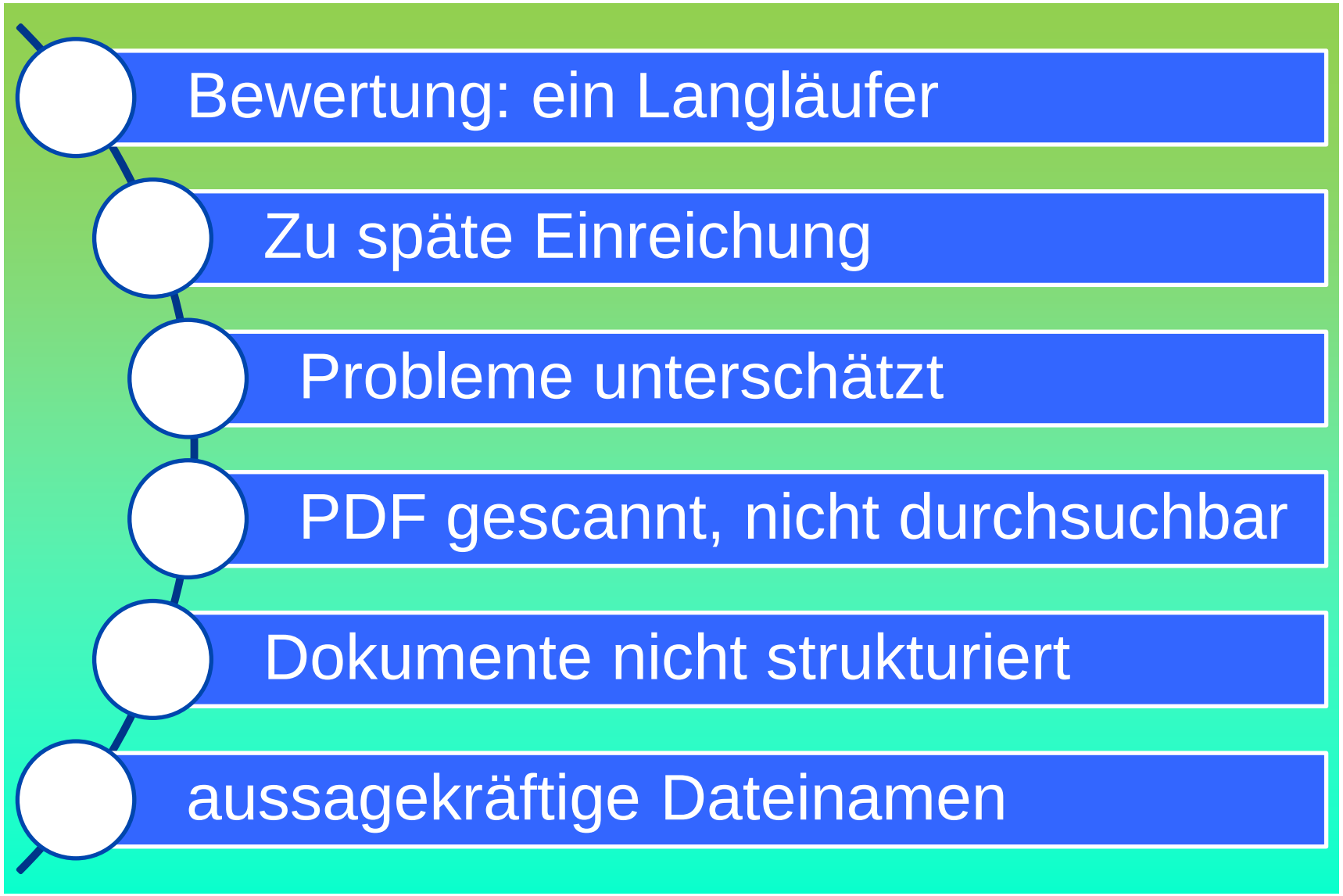
"On Site Audits"



TD Bewertung



TD Bewertung



Klinische Daten

Klinische Daten

Spezielle Nachweise

- Risk Management
  - ISO 14971
- Konstruktive Sicherheit
  - IEC 60601 ff
- EMV
  - IEC 60601-1-2
- Usability
  - IEC 62366

Spezielle Nachweise

Sterilisationsnachweise

- Bioburden
- Lohnsterilisierer
- Validierung

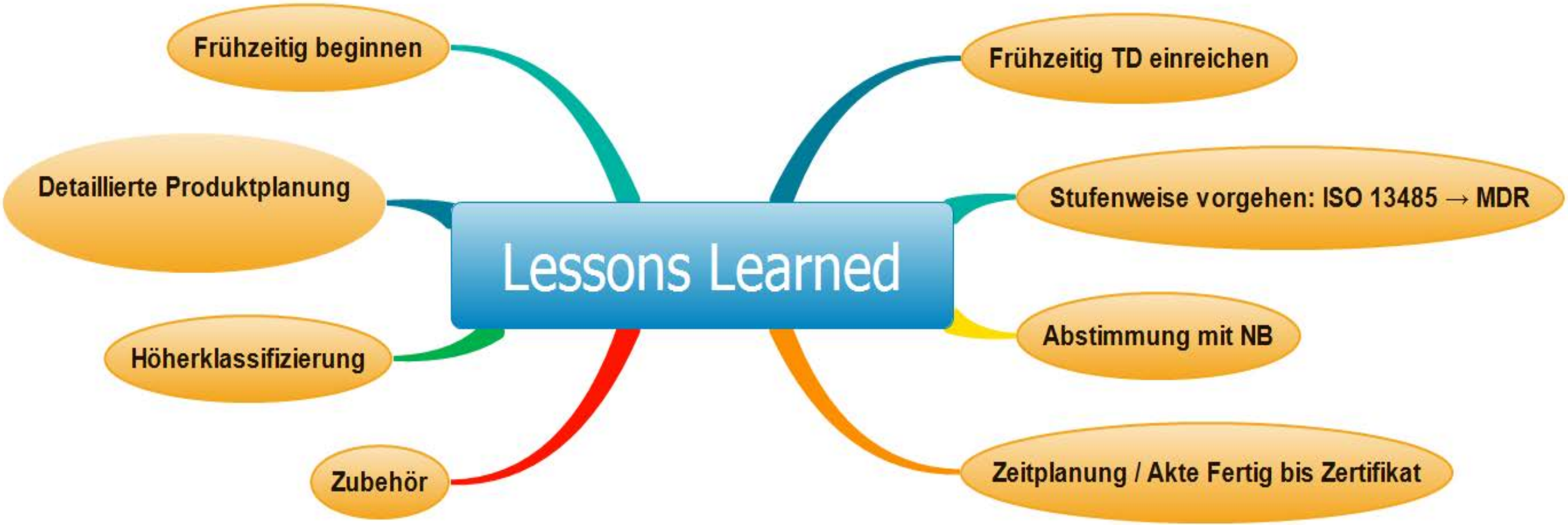
- Software

- IEC 62304,
- IEC 82304

- Cybersecurity

- IEC TR 60601-4-5
- MDCG 2019-16 Guidance on Cybersecurity for medical devices

„Lessons learned“:



Kontaktinformation:

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Mobil: +49 170 9168 451
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Active Medical Products AP1