
Dräger

Lübeck Summer Academy on Medical Technology 2021

July 2021, Lübeck

Dräger Roadmap – Preparing for the Medical Device Regulation

Volker Ständer

June 2021, Lübeck

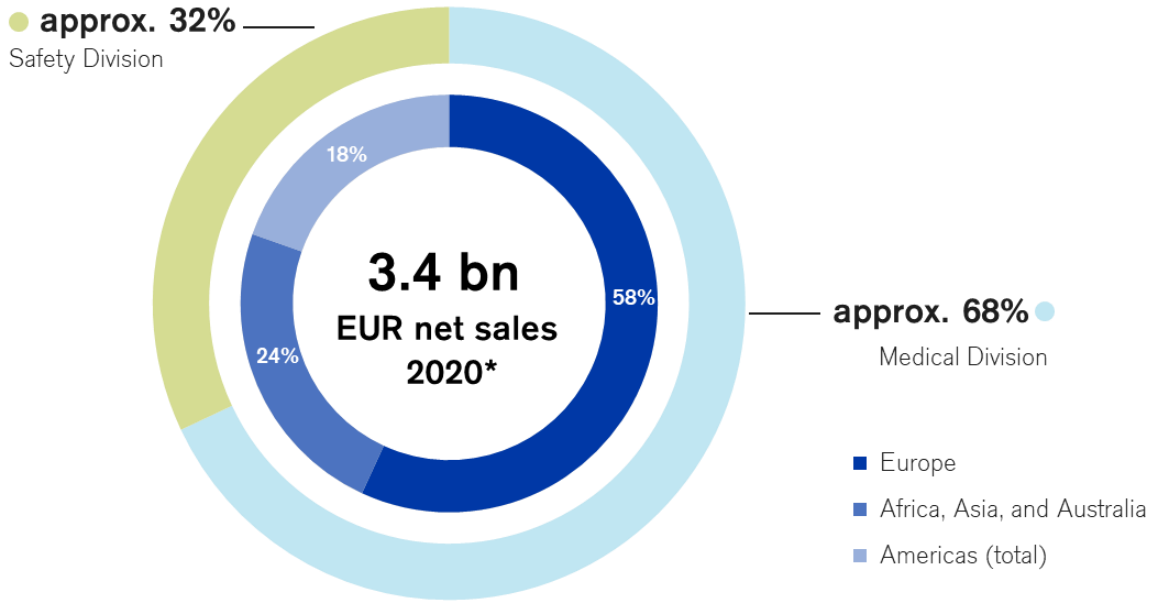
01

Dräger: short introduction

Dräger in profile

Figures from fiscal year 2020

Employees	15,657
Net sales	EUR 3,406.3 million
Chairman of the Executive Board	Stefan Dräger (family-run)
Form of business organization	AG & Co. KGaA
Headquarters	Lübeck, Germany
Production sites	Germany, Chile, China, France, U.K., India, Sweden, South Africa, Czech Republic, U.S.
Sales and service locations	In some 50 countries



02

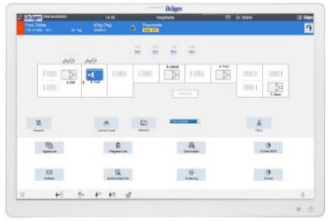
Which Dräger products are affected by the MDR?

Affected products Medical Division

Medical:

- Complete product portfolio
  - Hospital Consumables and Accessories (HCA)
  - Anethesia
  - Ventilation
  - Warming therapy
  - Monitoring
  - Workplace Infrastructure
  - IT & Systems





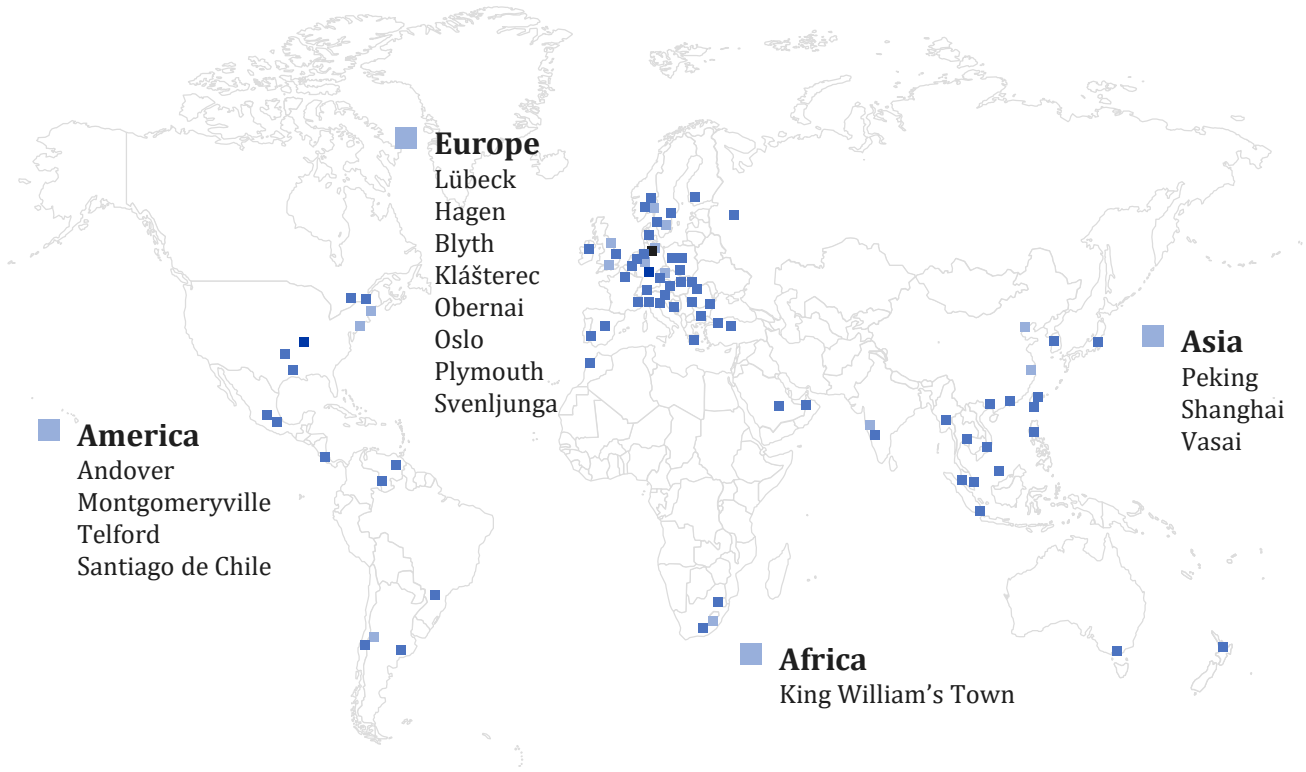
Typical risk classes:

I, Is, IIa, IIb, currently no product with risk class III

03

How is Dräger affected?

Dräger as economic operator



Dräger worldwide

- Headquarter in Lübeck
- Production sites in Europe, America, Africa and Asia
- Logistic centers in Europe and USA
- Sales and service locations worldwiide

Dräger as manufacturer

– Manufacturer
– Private Label Manufacturer
– Original Equipment Manufacturer

Dräger as authorized representative

Dräger as importer and distributor

Drägers roles and obligations

Dräger as legal manufacturer:

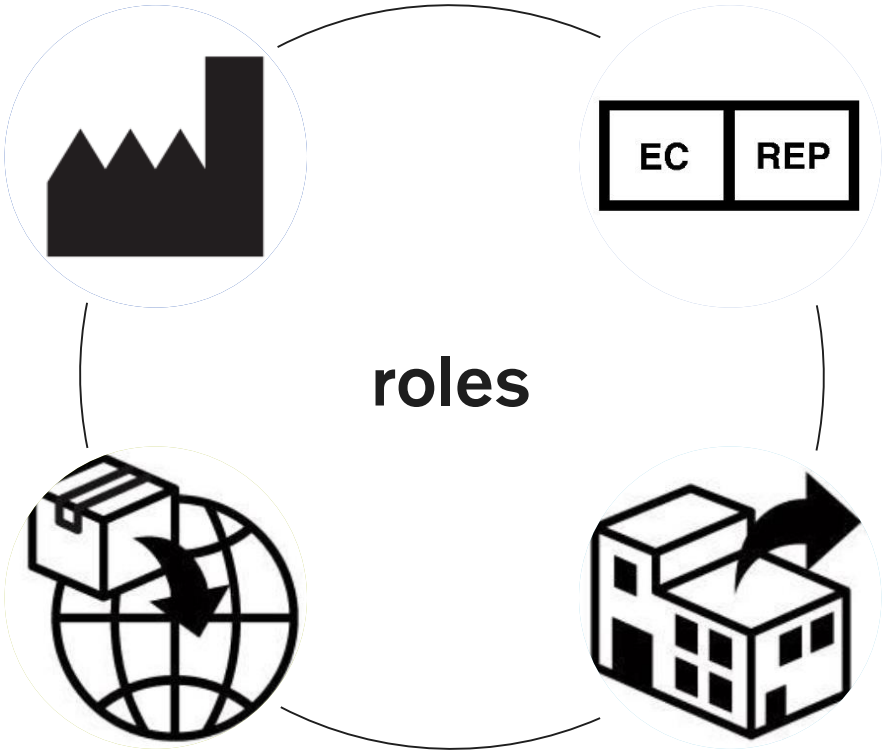
→ Obligations acc. article 10

- Drägerwerk AG & Co. KGaA
- Dräger Medical Systems, Inc.
- Shanghai Dräger Medical Instrument Co., Ltd.
- Dräger India Pvt. Ltd.

Dräger as importer:

→ Obligations acc. article 13

- Drägerwerk AG & Co. KGaA for DMSI, SDMI, DI & Tradeware
- Dräger S&S Subsidiaries in Europe (should be avoided)



Dräger as authorized representative:

→ Obligations acc. to article 11

Drägerwerk AG & Co. KGaA for

- Dräger Medical Systems, Inc. (DMSI)
- Shanghai Dräger Medical Instrument Co., Ltd. (SDMI)
- Dräger India Pvt. Ltd. (DI)

Dräger as distributor:

→ Obligations acc. article 14

- Drägerwerk AG & Co KGaA
- Dräger S&S Subsidiaries in Europe

Facts and figures for the Medical Division

The MDR trigger substantial changes affecting **products**, **processes**, **functions** and **IT systems** at Dräger,

- Product changes vary from simple to very complex

Project complexity data:

– 1.300 MDR requirements, thereof 330 are new to Dräger

– 300 Tech Files with >3.000 products require MDR update

– 100 OEM/Private Label products and 500 tradeware products need discussion with supplier

– >1.000 cl. I products with readiness date 5/2021

– ca. 1.000 components require substance evaluation (>1.200 CMR and ED substances each)

– 3.000 device label and 3.000 IfU to be considered, plus IfU translation to >10 languages

– 5 development sites und 4 legal manufacturer in 4 countries affected (Germany, 2x USA, India, China). >15 departments involved

Changeover costs benchmark: 2-5% of sales (source: Ernst & Young Life Sciences) → Changeover costs estimated: €20-30 million

Not only manufacturers are affected; the demand for recertification will keep Notified Bodies busy.

Notified Body

Dräger’s Notified Body TÜV Süd was designated as a Notified Body according to MDR at an early stage

Press release Mai 2019:

„TÜV SÜD BECOMES SECOND NOTIFIED BODY RECEIVING DESIGNATION.“
TÜV SÜD Product Service is among the world's first certification bodies to receive designation as a Notified Body for the new Medical Device Regulation (MDR) by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG). The

Advantages for Dräger:

– Dräger was able to continue working with TÜV Süd.
– Dräger was able to apply for MDR certification at an early stage.

04

Dräger as legal manufacturer – General procedure

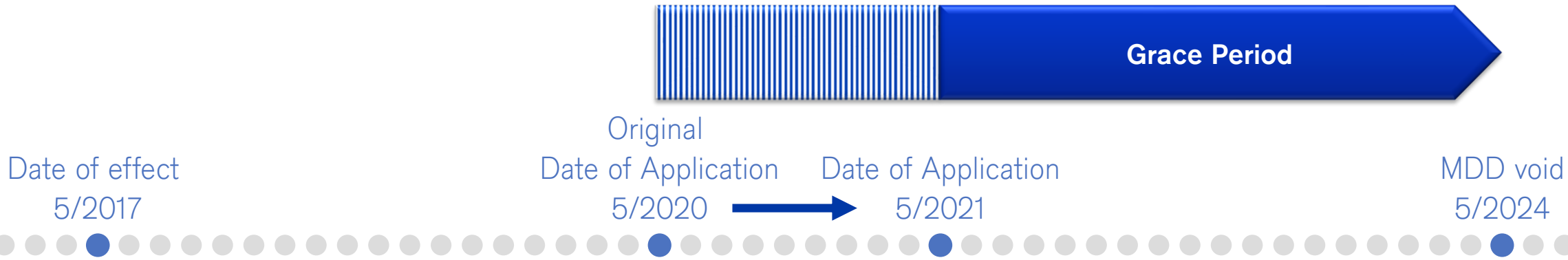
MDR timeline – MDD certification renewals

Extension of MDD certificates to make the most of the Grace Period.

Almost all MDD certificates from Draeger are valid until the end of the Grace Period.

– This allows us more flexibility regarding updating products and technical documentation..

– Products that are not updated to MDR can continue to be sold during the Grace Period as long as no significant product changes are made acc. to Article 120 (3)



MDR – GAP analysis in 2017

Analysis & Planning

- Technical File
- Labelling
- Clinical
- Substances
- Risk Mgmt.
- PMS
- OEM/PLM/TW
- QMS

work streams

Verordnung (EU) 2017/745 über Medizinprodukte

Updating Dräger‘s quality management system

Updating products und technical documentation

05

Path to MDR-compliant quality management system

Qualtiy management system

Annex IX is relevant for Draeger:

„CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION"

ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

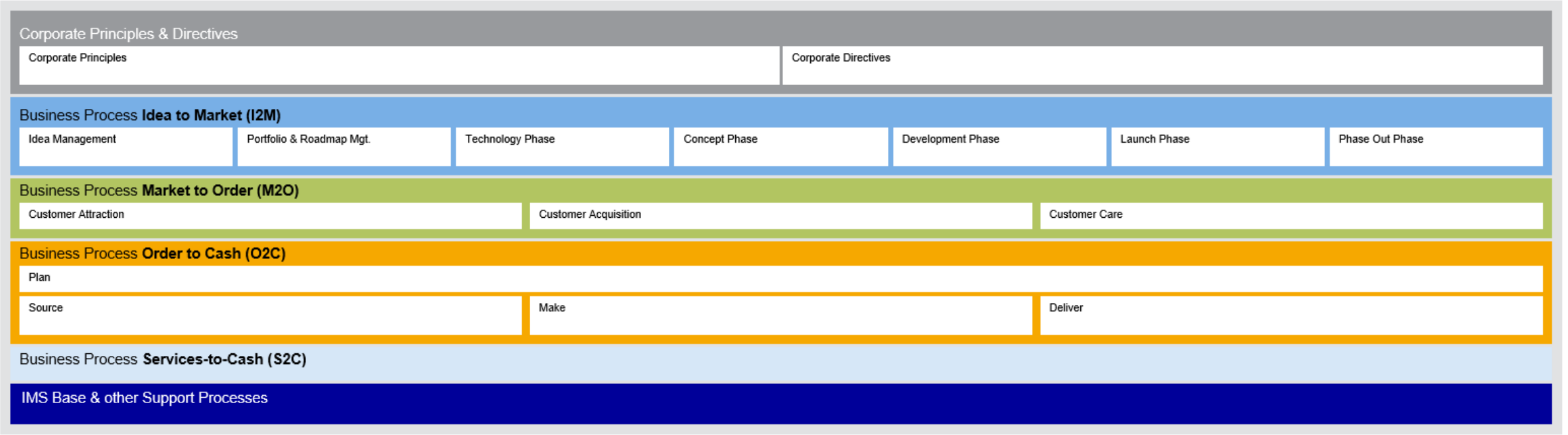
CHAPTER I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management system as described in Article 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2 and shall be subject to audit, as laid down in Sections 2.3 and 2.4, and to surveillance as specified in Section 3.

Qualtiy management system

Quality management system



A fully comprehensive QMS that already meets many requirements (MDD, 21 CFR part 820, ISO 13485, ...) is in place, but compliance with the MDR must be verified.

All processes exist as global SOP, which are then transferred to local versions.

Gap analysis quality management system

Qualtiy management system

Chapter	Chapter Name	Article	Article Decription	Number	Text	Substantial change for Dräger
2	Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement	10	General obligations of manufacturers	1	1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.	N
2	Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement	10	General obligations of manufacturers	2	2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.	N
2	Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement	10	General obligations of manufacturers	3	3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.	Y

GAP analysis

MDR requirements vs. existing Dräger processes.

Result of the GAP analysis:

330 requirements require an adjustment at Dräger.

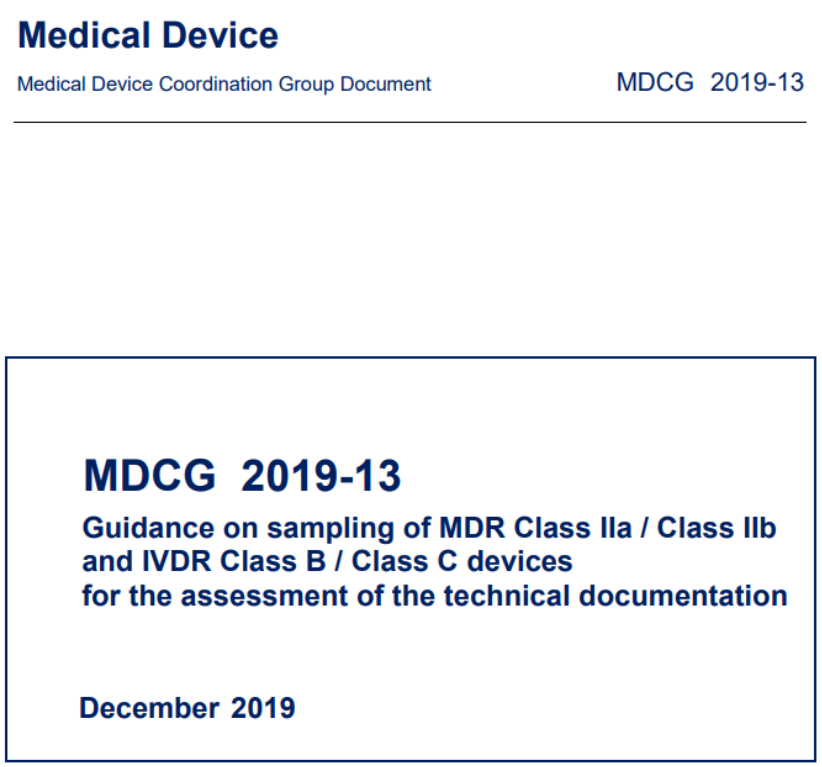
Assignment to the appropriate workstream to develop solutions.

Changes to processes and templates
– Development of processes, procedures and templates
– Changes to IT systems

06

Path to MDR certificats

Assessment of technical documentation



Annex IX is relevant for Draeger:

„CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION"

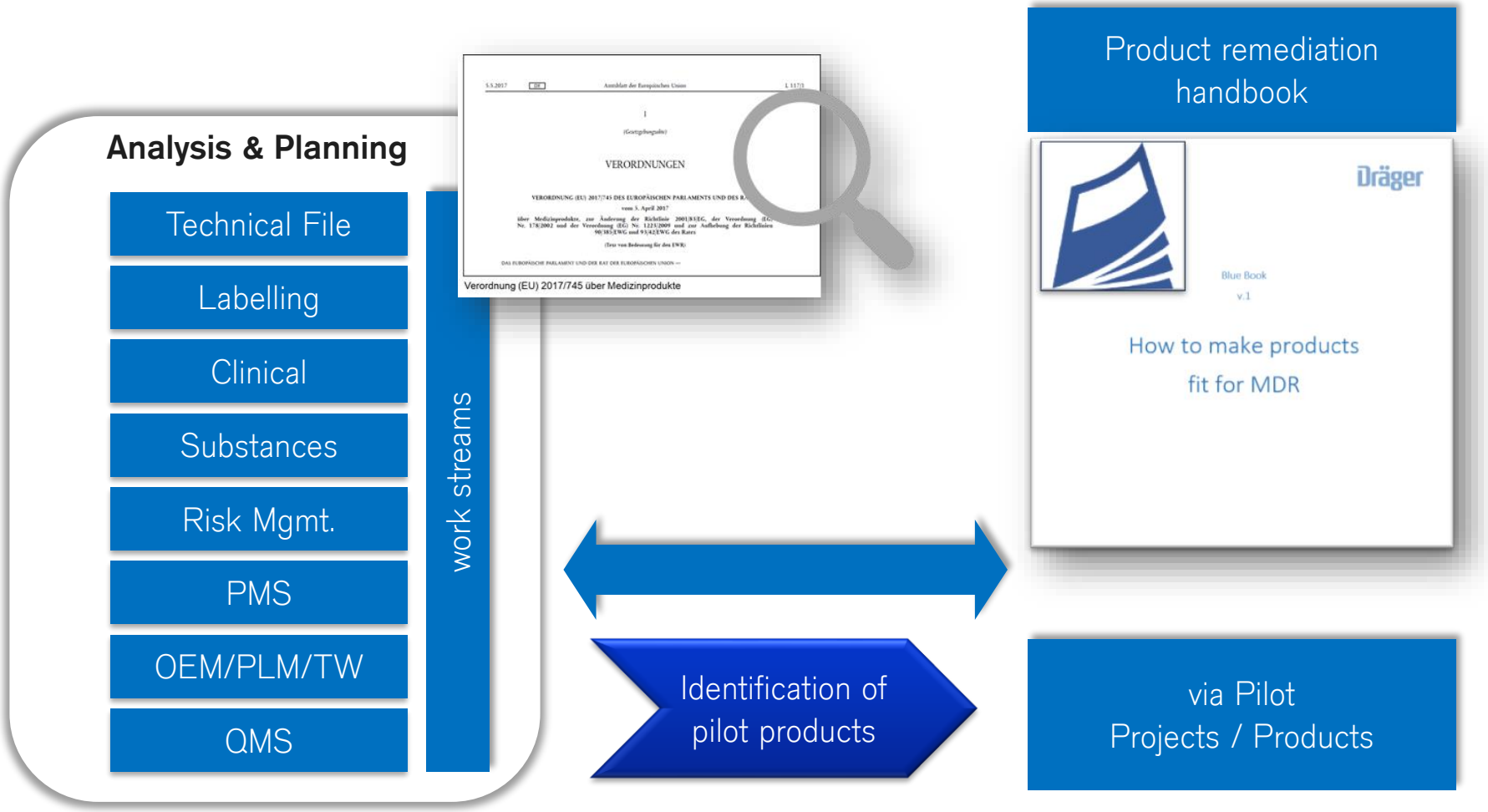
Sampling

Article 52(4) and (6) of the MDR and Article 48(7) and (9) of the IVDR establish the need to assess the technical documentation of at least one representative device per generic device group (for Class IIb and Class C) and for each category of devices (for Class IIa and Class B) prior to issuing the certificate.

Classification of our products in the EMDN and MDA/MDN codes and alignment with our Notified Body.

Identify products whose Technical Documentation will be sent to our Notified Body for assessment.

Pilot projects & Blue Book



Pilot projects :

- Polaris 600 surgical light (Class I)
- Central station hoses (Class IIa)
- Savina 300 ventilator (Class IIb)

Close cooperation with MDR workstreams

- Direct support for the projects
- Review of proposed solutions
- Feedback from projects was incorporated into the blue book and processes

Pilot projects & Blue Book

Analysis & Planning

- Technical File
- Labelling
- Clinical
- Substances
- Risk Mgmt.
- PMS
- OEM/PLM/TW
- QMS

work streams

Identification of pilot products

Product remediation handbook

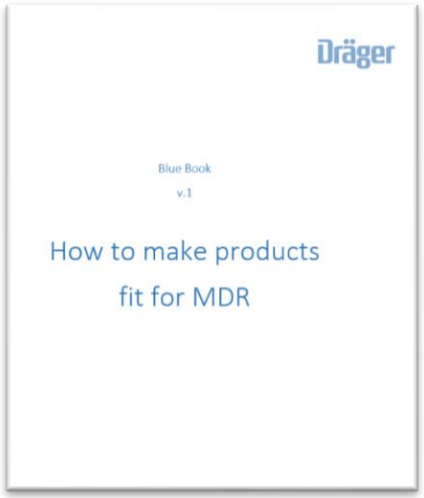
Regular updates

via Pilot Projects / Products

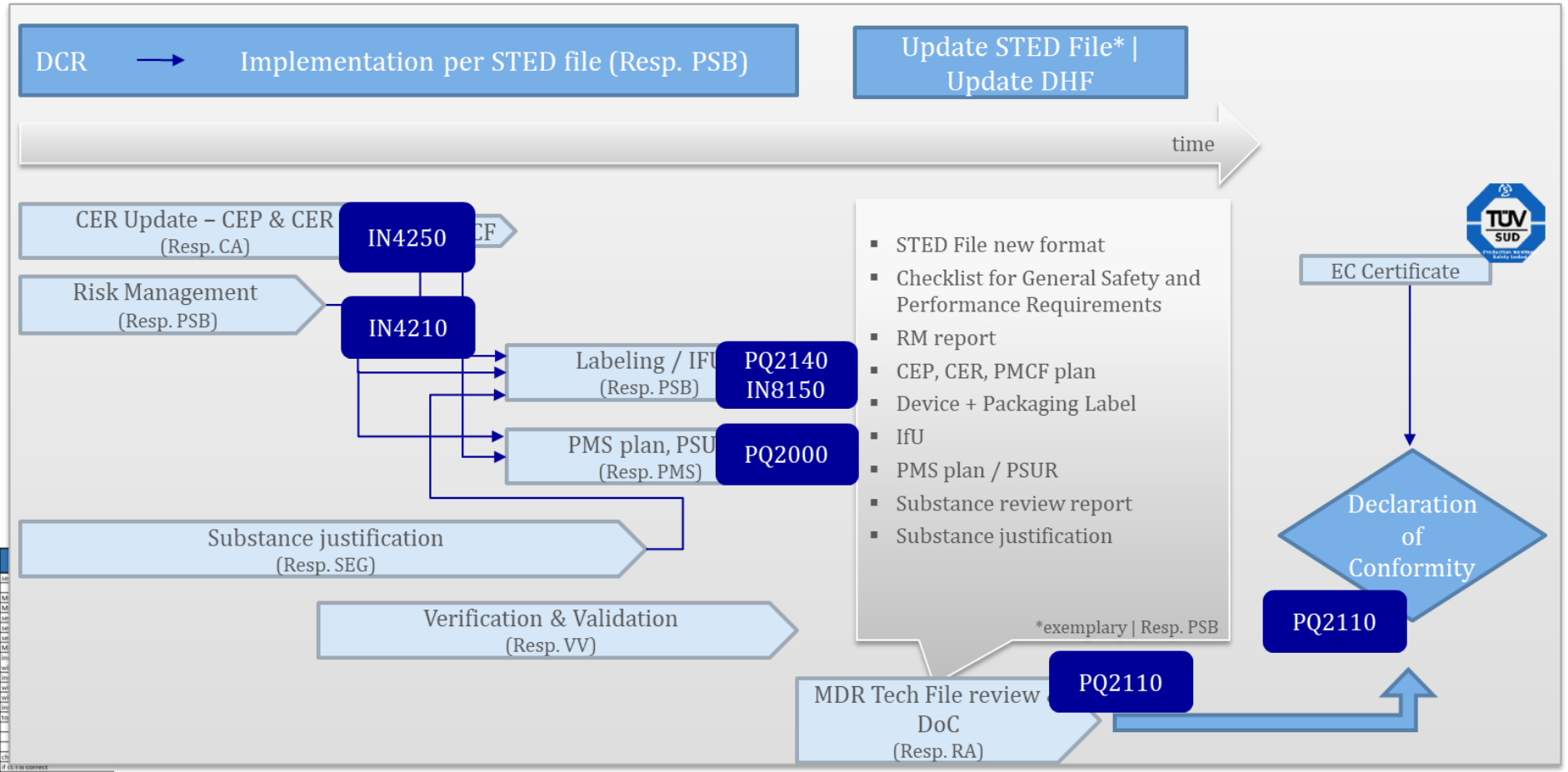
Handover to China, USA, India and all projects in Germany

Product update

Remidiation roadmap



Program	Product	New Product Introduction/ Series device	risk class	End of production	change to MDR y/n	start date	end date	
WPI	AIM	Series device	I		yes	01.07.18	01.05.20	se
WPI	Demokrit	Series device			yes	01.06.2018	01.02.19	
WPI	Gas Control Systems	Series device			yes			M
WPI	Compressed Air Systems	Series device			yes			M
WPI	Vacuum Systems	Series device	I		yes	01.07.18	01.05.20	se
WPI	Alarm Systems	Series device	I		yes	01.07.18	01.05.20	se
WPI	Terminal Units	Series device	I		yes	01.07.18	01.05.20	se
WPI	Distribution Systems	Series device			yes			M
								in
A	Perseus A500 Rel. 3	NPI project			yes		01.10.21	wi
A	A350 Rel. 2.0n MRI	NPI project			yes		01.10.21	in
A	A350 Rel. 2.5n	NPI project			yes		01.10.20	wi
A	A350 Rel. 3.0n	NPI project			yes		01.10.20	wi
A	A150	NPI project			yes		01.10.20	in
A	Powerstrip (SHA)	NPI project	I		yes	01.05.2019	01.05.20	to
A	Vapor 2000	Series device			yes		01.05.20	
A	Vapor 3000	Series device			yes		01.05.20	
A	D-Vapor 2000	Series device			yes		01.05.20	
WT	Isolette 8000 Plus	Series device			yes	01.05.2019	01.05.20	ch
WT	Isolette C2000	Series device	I		yes	01.05.2019	01.05.20	if CE is correct
WT	Billux	Series device	IIa		yes	01.06.2019	01.05.20	discuss with supplier
WT	JM105	Series device	IIa		yes		01.05.20	discuss with supplier/TF
WT	JM successor	NPI project			yes		01.10.23	discuss with supplier/HL
WT	Mira Cradle	NPI project			yes		01.05.20	
WT	TI500	Series device			yes	01.05.2019	01.05.20	end date tbd / transport under discu
RC	Savina 300	Series device			yes	01.02.2018	01.09.19	Pilot / check with TÜV in 2018? 2019
RC	Carina	Series device			yes		01.02.21	



MDR timeline – process & product update

Analysis & Planning

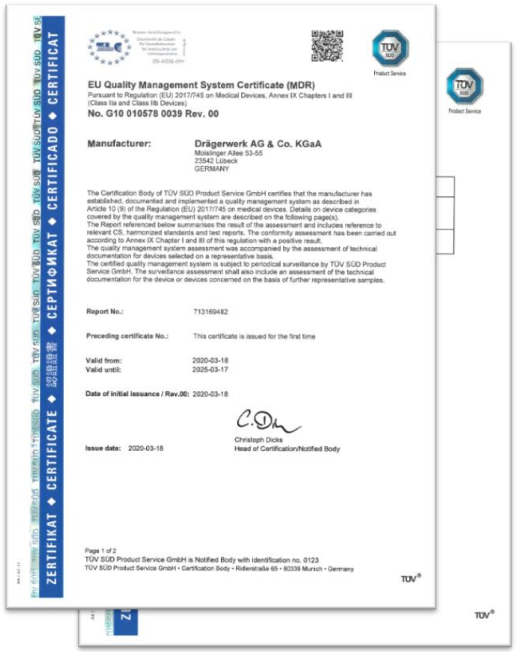
- Technical File
- Labelling
- Clinical
- Substances
- Risk Mgmt.
- PMS
- OEM/PLM/TW
- QMS

work streams

The global process changes were implemented in 2018.

Initial QMS audit (Stage II) for Drägerwerk AG was successfully completed in September 2019.

MDR certificate received for Drägerwerk AG in March 2020 for two product scopes.


EU Quality Management System Certificate (MDR)

No. G10 010578 0039 Rev. 00

Manufacturer: Drägerwerk AG & Co. KGaA

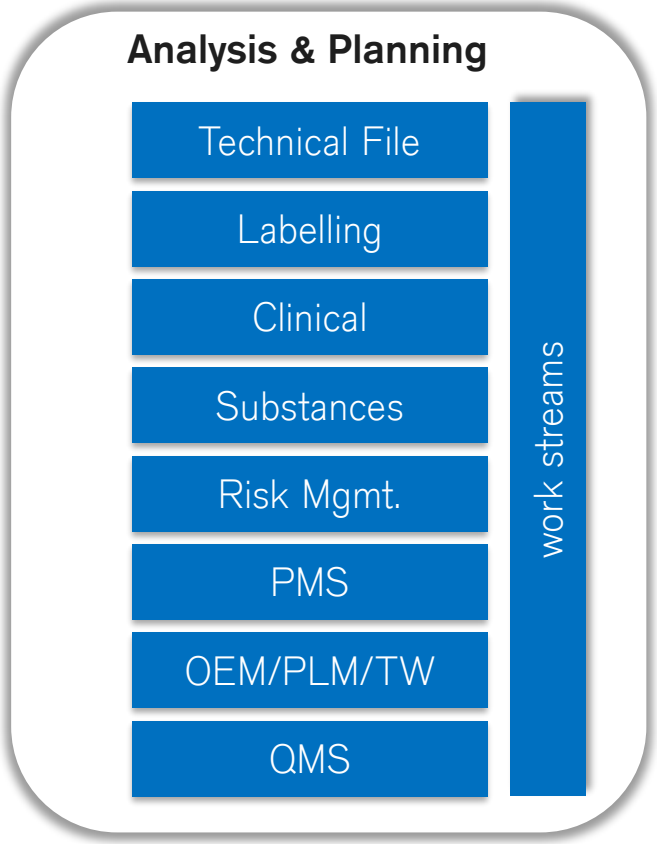
MDR compliance for pilot products and processes

Date of effect 5/2017

Date of Application 5/2021

MDD void 5/2024

MDR timeline – roadmap product update



Placing new products on the market according to MDR.

Update the products with risk class IIa / IIb.

Grace period for product of risk class IIa / IIb

Phase out of products (IIa / IIb) not updated to MDR

Update products with risk class I.

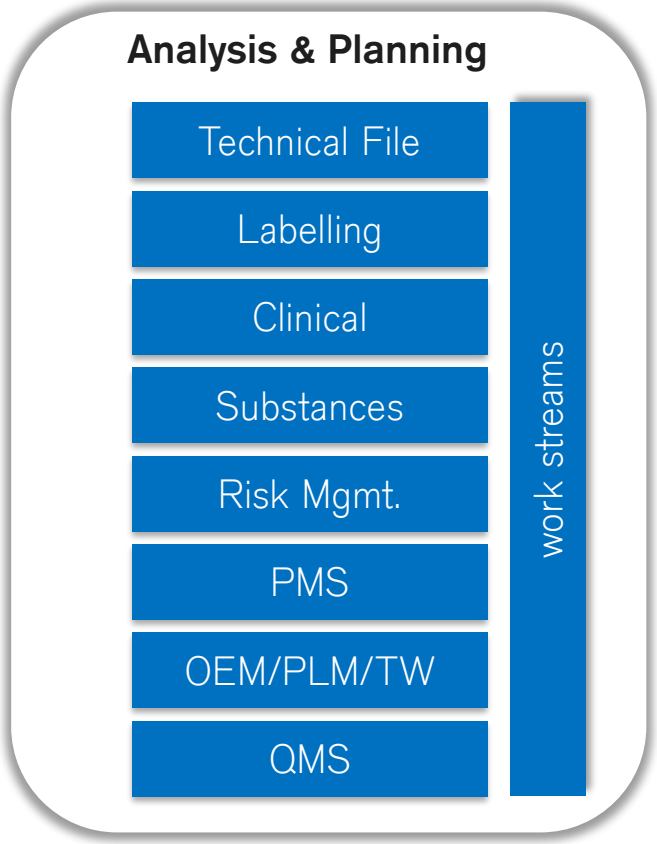
MDR compliance for pilot products and processes

Date of effect 5/2017

Date of Application 5/2021

MDD void 5/2024

MDR timeline – roadmap product update



Placing new products on the market according to MDR.

Precise scheduling of the update projects is carried out in coordination with the Dräger development roadmap.

- **Deciding which products to update to MDR**
- **Timing of the update projects**

Goal:
combine MDR update with other product changes where possible

MDR compliance for pilot products and processes

Date of effect
5/2017

Date of Application
5/2021

MDD void
5/2024

MDR timeline – Extension of the MDR certificate

Analysis & Planning

- Technical File
- Labelling
- Clinical
- Substances
- Risk Mgmt.
- PMS
- OEM/PLM/TW
- QMS

work streams

Update the products with risk class IIa / IIb.

Tech File Review

Tech File Review

Tech File Review

Extension with three product scopes expected in early 2021. Plus, files for 9 scopes in review.

MDR compliance for pilot products and processes

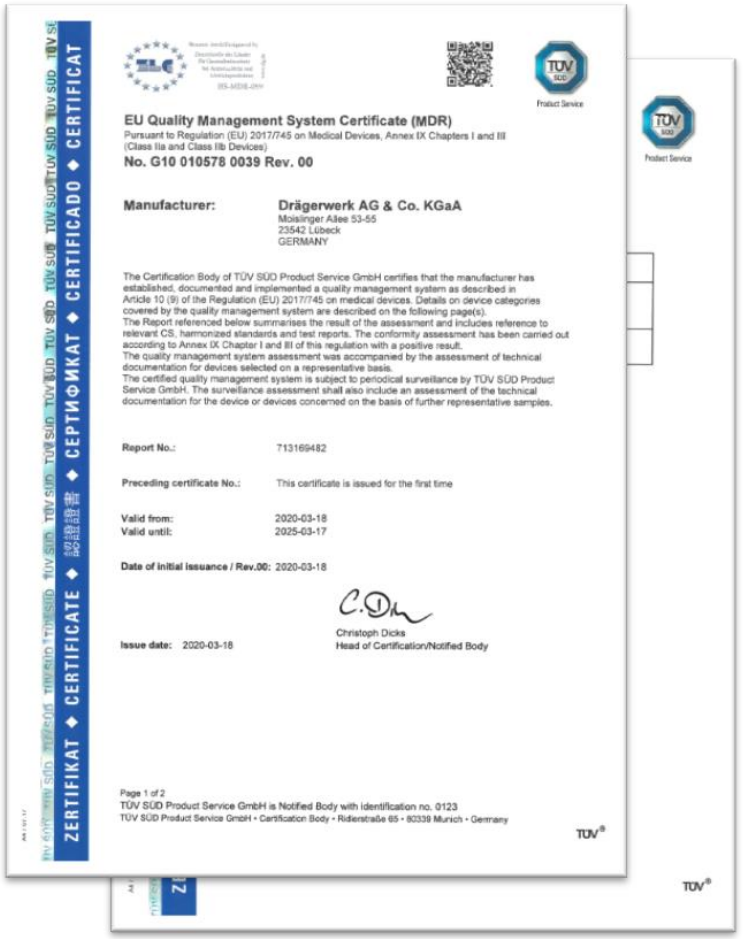
Scope extension on the MDR certificate

Date of effect
5/2017

Date of Application
5/2021

MDD void
5/2024

MDR certification of the other legal manufacturers



EU Quality Management System Certificate (MDR)
Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)
No. G10 010578 0039 Rev. 00

Manufacturer: Dräger werk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713169482
Preceding certificate No.: This certificate is issued for the first time
Valid from: 2020-03-18
Valid until: 2025-03-17
Date of initial issuance / Rev.00: 2020-03-18

Issue date: 2020-03-18
Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

USA, China, India

– The local quality management systems have been updated to MDR.

– Working on product updates

– Audit planning takes place in alignment with the product update roadmaps and our Notified Body.

– Planning of the on-site audits (Stage II) was difficult due to Corona and the associated restrictions.

07

Dräger as legal manufacturer - IT changes

MDR Timeline – IT changes

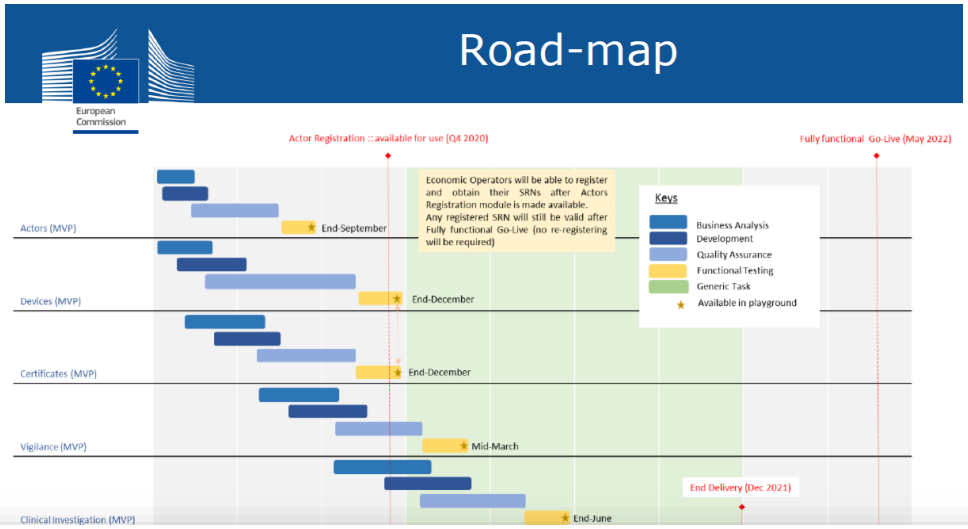
Analysis & Planning

- Technical File
- Labelling
- Clinical
- Substances
- Risk Mgmt.
- PM
- OEM/PL
- QMS

work streams

Verordnung (EU) 2017/745 über Medizinprodukte

EUDAMED



ANNEX VI - INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOM TORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM

UDI data, IT projects, EUDAMED

Date of effect
5/2017

Date of Application
5/2021

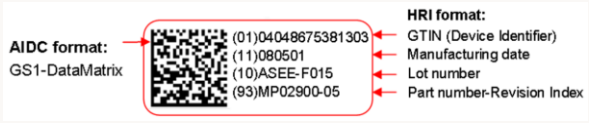
MDD void
5/2024

UDI System

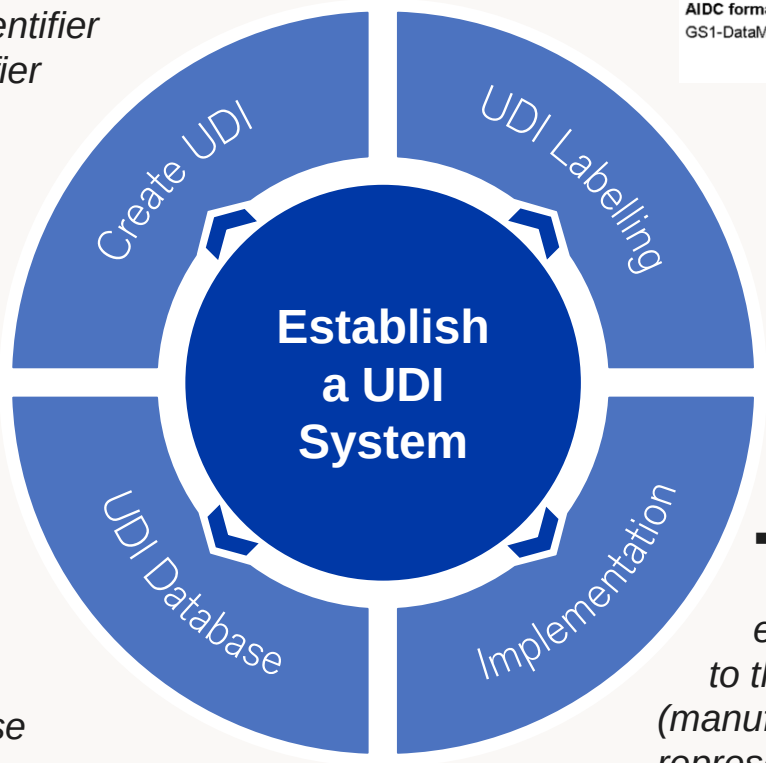
Develop a standardized system to create the Unique Device Identifier

- *UDI = DI + PI; DI, Device Identifier (static),PI, Production Identifier (dynamic)*
- *UDI Carrier:*
  - *Machine readable*
  - *Human readable*
- *observe allowed issuing agencies*

Place UDIs on packaging labels and (if applicable) on the device



- *Apply a UDI to each packaging level of a medical device packaging structure*
- *If applicable, apply direct marking to medical device*



Create and maintain UDI database

- *before placing a device on the market, static UDI data elements (allergen, GMDN, sterility, etc.) must be provided to the UDI database*
- *IMDRF requires > 50 data elements per product*
- *UDI databases are publicly accessible*

Adoption and implementation by all stakeholders

- *UDI requirements needs to be implemented by all economic operators according to their respective obligations (manufacturer, importer, authorized representative, tradeware partners, users, logistic chains, etc.)*

- Collect UDI data
- Participate in EUDAMED playgrounds
- Create Dräger UDI database
- Prepare M2M connetion to EUDAMED

08

Dräger as authorized representative, importer and distributor

Authorized representative, importer and distributor

Drägerwerk AG act as authorized representative and importer

– Dräger Medical Systems, Inc.,
– Shanghai Dräger Medical Instrument Co., Ltd.
– Dräger India Pvt. Ltd.

– Update agreements

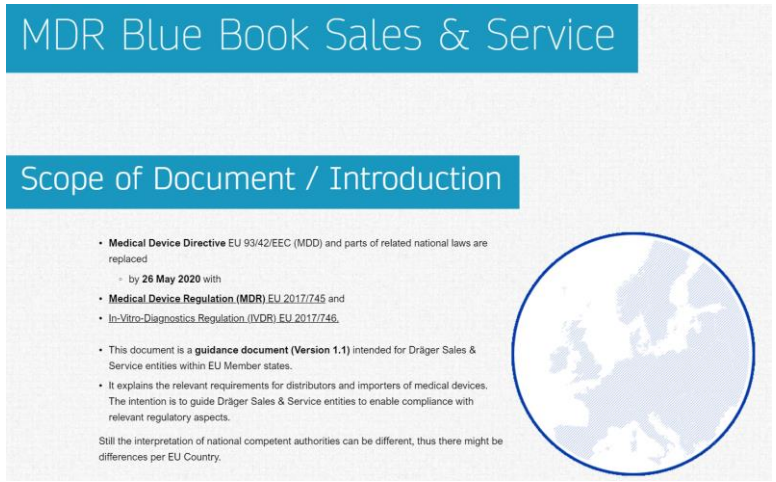
– File Technical documantation in our approval IT tool (Owner DWAG)
– Update Label
– Registration in EUDAMED

Drägerwerk AG as distributor:

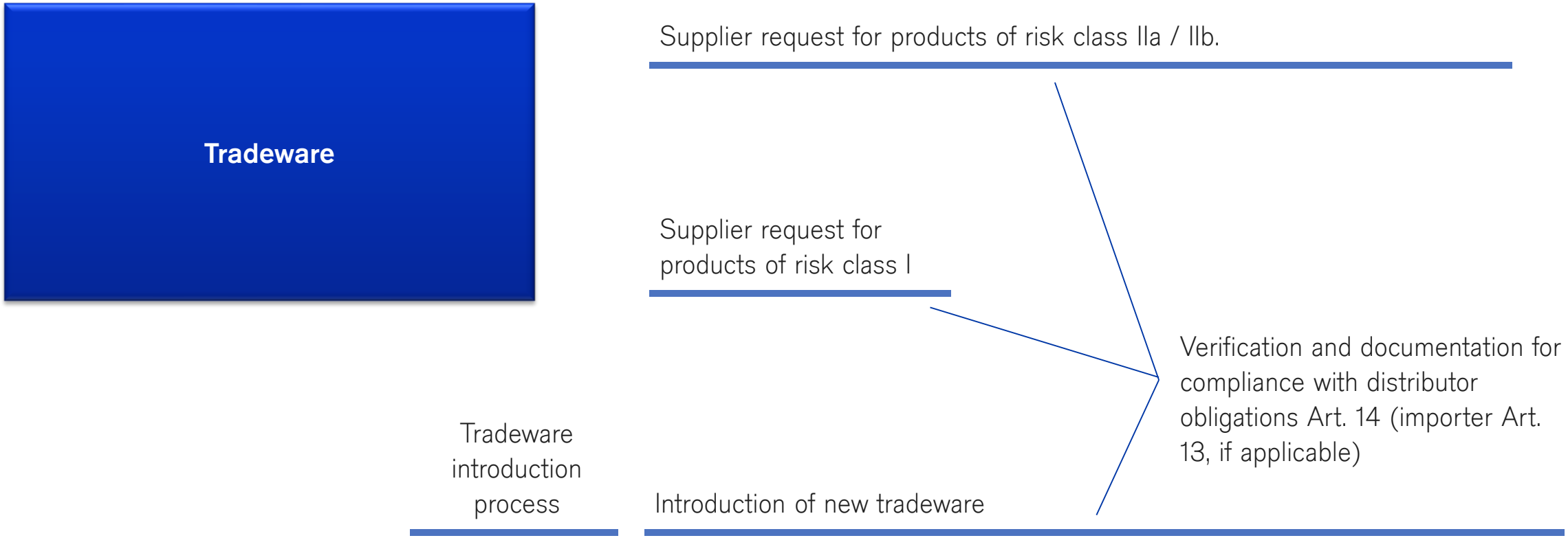
– Tradeware
→ Request needed MDR information from our supplier, establish tradeware introduction process

Dräger Sales & Service subsidiaries in Europe:

– Process updates
– Sales & Service Blue Book that describes the procedures for ensuring the distributor obligations of the MDR.



Process- & product update



09

Conclusion

Success factors

Commercial evaluation of the product conversion to MDR: Which products do we convert to MDR?

When planning the initial update roadmap, but also as it progresses.

Link MDR change with product change.

Experienced and well-connected experts:

Dräger is represented in 3 MDCG Working Groups as a representative from SPECTARIS / EUROM VI:
– WG 3 - Clinical investigation and evaluation
– WG 4 - Post-market surveillance and vigilance
– WG 10 - International Affairs

Questions?

Thank you

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