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 072017 0015 Rev. 00

Manufacturer: MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

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.: 713170827

Preceding certificate No.: This certificate is issued for the first time

Valid from: 2020-02-17
Valid until: 2025-02-16

Date of initial issuance / Rev.00: 2020-02-17

Issue date: 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

Lessons learned from MDR implementation

Swedish MedTech Regulatory Summit

Stockholm, 20 February 2020

Senior Advisor
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Mikael K Johansson

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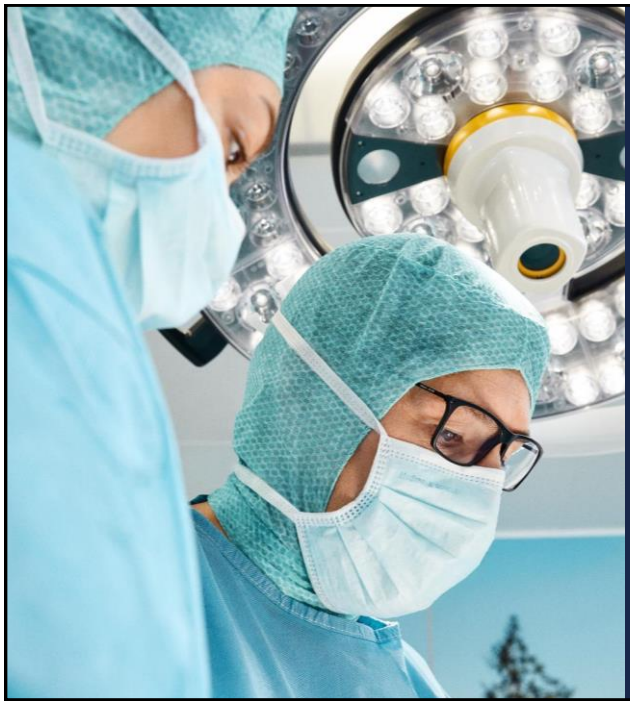

This is Getinge

With passion for life

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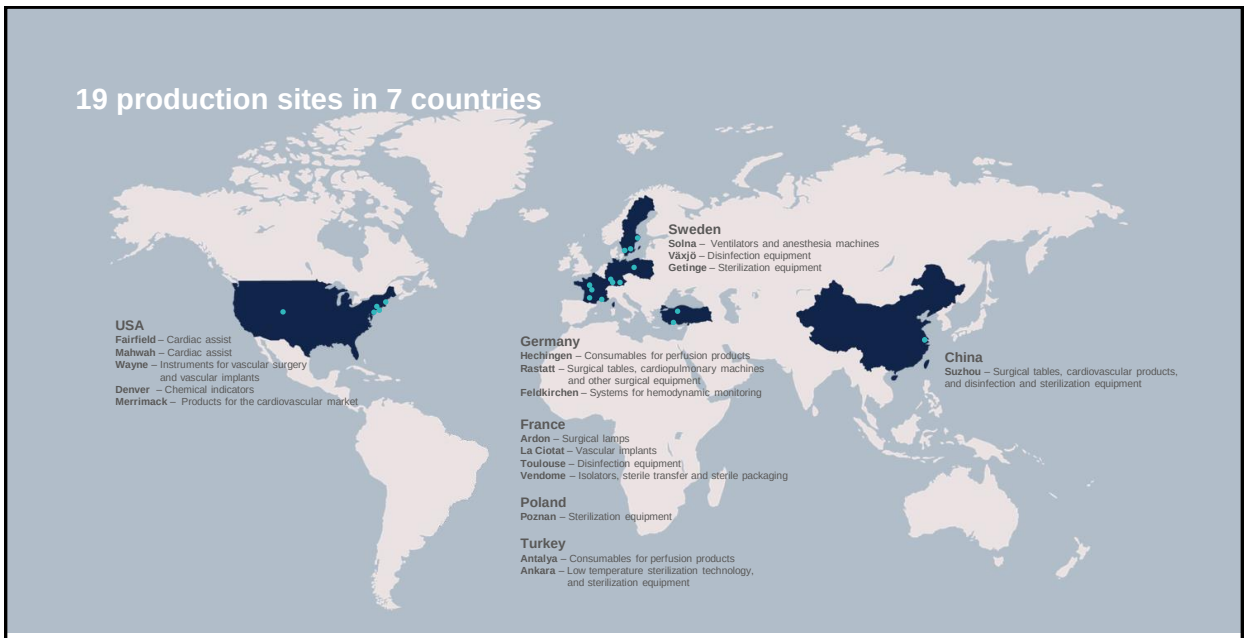

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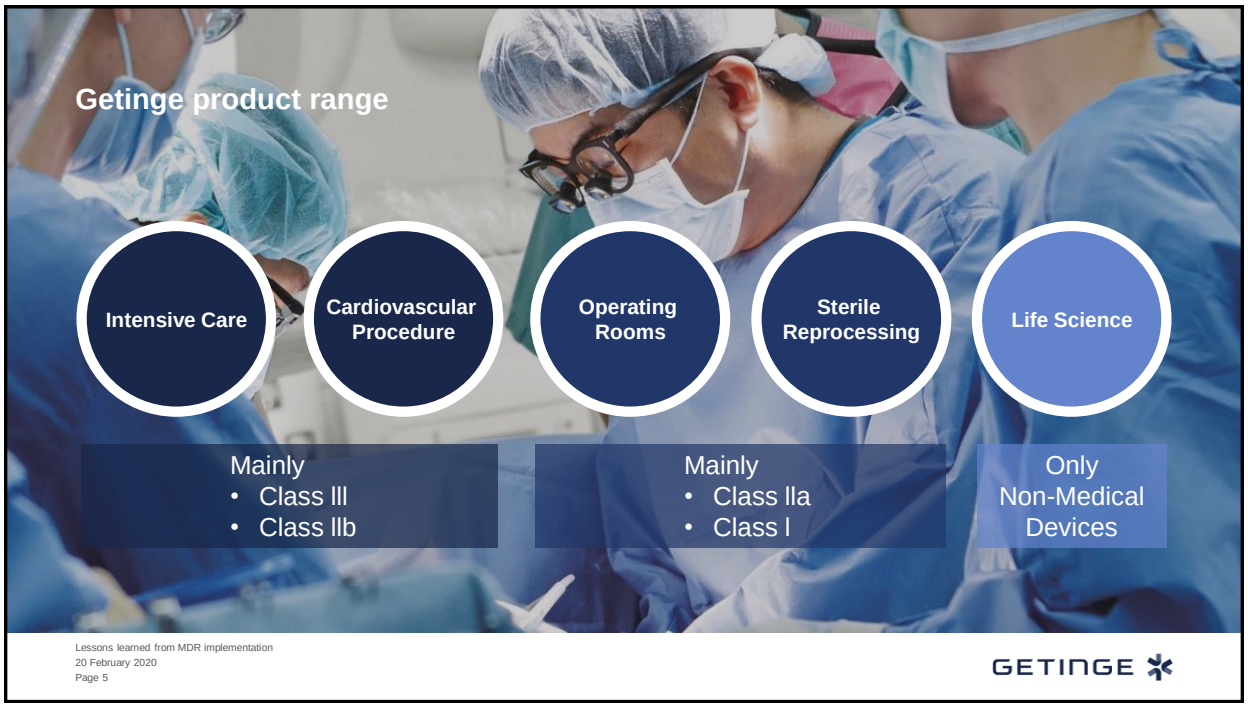
Getinge product range
Intensive Care
Cardiovascular Procedure
Operating Rooms
Sterile Reprocessing
Life Science
Mainly
• Class III
• Class IIb
Mainly
• Class IIa
• Class I
Only Non-Medical Devices
Lessons learned from MDR implementation
20 February 2020
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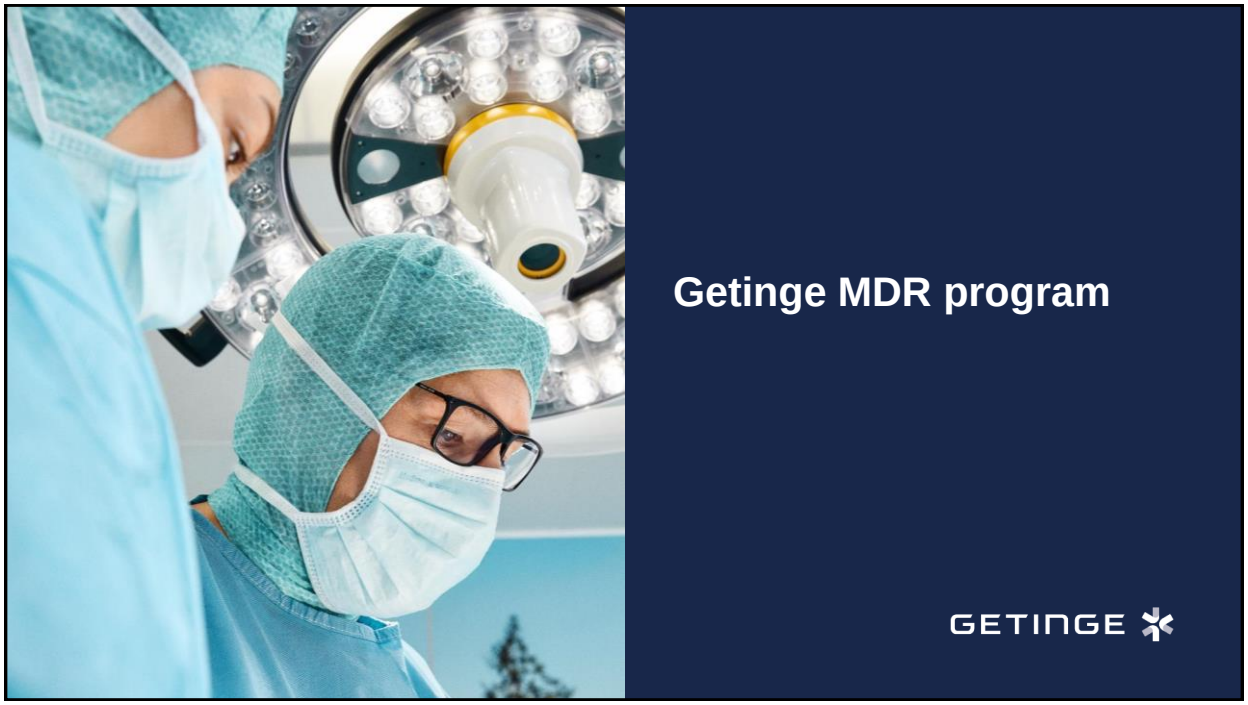
Getinge MDR program
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Getinge MDR Program

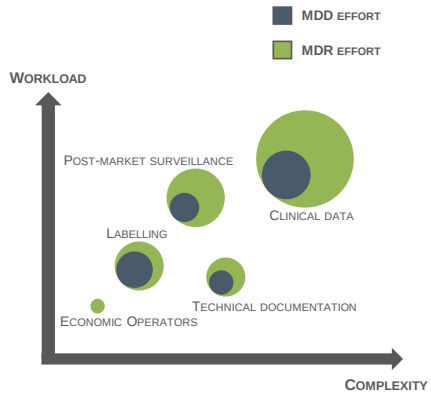
Major CHANGES in effect of MDR vs. current legislation MDD

MDD

- **DIRECTIVE** BY THE EUROPEAN COMMISSION REGULATING MEDICAL DEVICES ISSUED 1993 AND **EFFECTIVE 1995**.
- DIRECTIVE IS IMPLEMENTED BY EU MEMBER STATES IN NATIONAL LAW.
- COMPLIANCE MONITORED CURRENTLY BY APPROX. 55 NOTIFIED BODIES.

MDR

- **LAW** BY THE EUROPEAN COMMISSION REGULATING MEDICAL DEVICES ISSUED 2017 AND **EFFECTIVE MAY 2020**.
- COMPLIANCE CURRENTLY MONITORED BY 11 NOTIFIED BODIES DESIGNATED FOR MDR AS OF FEBRUARY 13, 2020.
- 20 NOTIFIED BODIES EXPECTED TO BE DESIGNATED BY Q1 2020.



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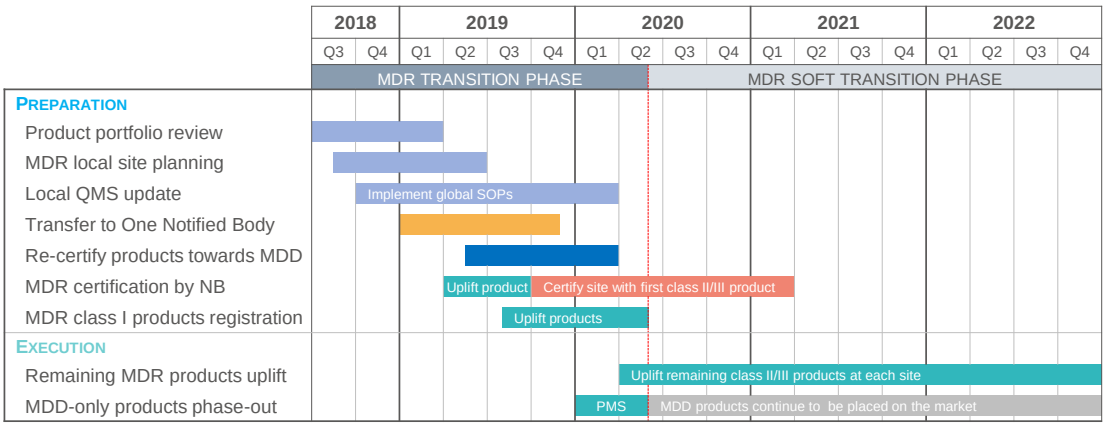
Getinge MDR Program

Plan for site transfers



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Getinge MDR Program

Lessons learned

1. Significant reduction of the product portfolio
2. Ensure Notified Body access
3. Consolidate all sites to One Notified Body
4. TOP Management attention and separate MDR program / Project
5. Early pilot with MDR certification of one site and product

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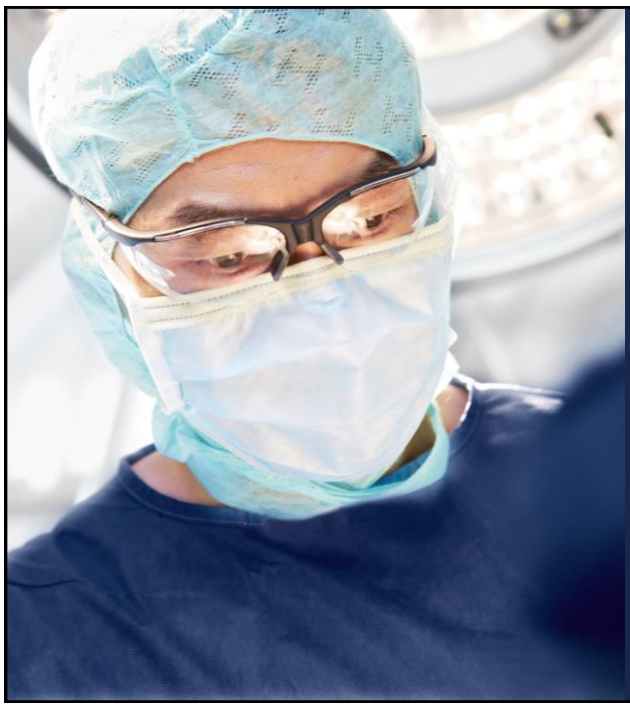

Takeaways from the Getinge MDR certification

at Maquet Critical Care Solna, October 2019

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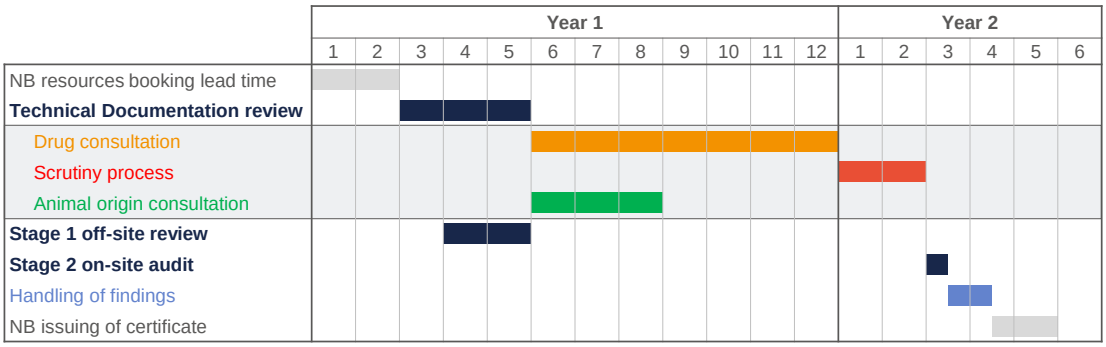
MDR certification process

Class III & IIb implantables (“complex”)



Total certification cycle: 17 months

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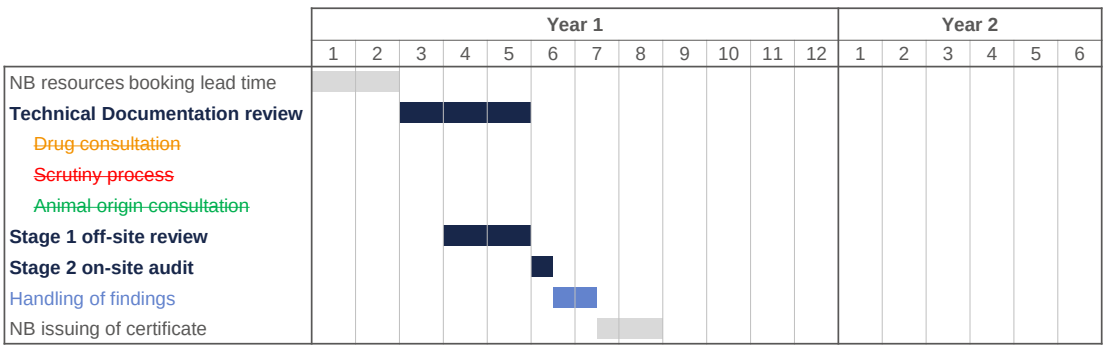
MDR certification process

“Easy products” > class I



Total certification cycle: 8 months

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Technical Documentation review

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Takeaways from the MDR certification

Technical Documentation review

- Additional documents were requested:
  - IFUs
  - Product risk management: All
  - Traceability matrices
  - Packaging types/descriptions

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Takeaways from the MDR certification

Technical Documentation review

- High focus during review and detailed questions related to:
  - **Functional Safety**
    - New concept. The Notified Body requested details on single-fault safety that goes beyond ISO 14971, IEC 60601 etc.
  - **Cybersecurity**
    - Increased focus from the Notified Body compared to previous (MDD) reviews.

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Stage 1 off-site review

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Takeaways from the MDR certification

Stage 1 off-site review

- The Notified Body requested Getinge to send the QMS procedures that cover a specified list of topics.
- Based on the received questions from the Stage 1 review focused on:
  - Internal Audit on the MDR implementation
  - Implementation of Person Responsible for Regulatory Compliance (PRRC)
  - Handling and implementation of Economic Operators
  - Clinical Evaluation and Clinical Investigations
  - Risk Management and Cybersecurity

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Stage 2 on-site audit

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Takeaways from the MDR certification

Stage 2 on-site audit – 8 man days MDSAP audit with 3 man days of MDR focus

	Day 1	Day 2	Day 3
AM	*No separate MDR session*	Vigilance PMS PMCF	Clinical Investigation Clinical Evaluation
PM	Mgmnt Responsibility MDR certification strategy Basic UDI-DI & UDI PRRC Risk Management IFU translation	CAPA Technical Documentation	Economic Operators Production and Process controls

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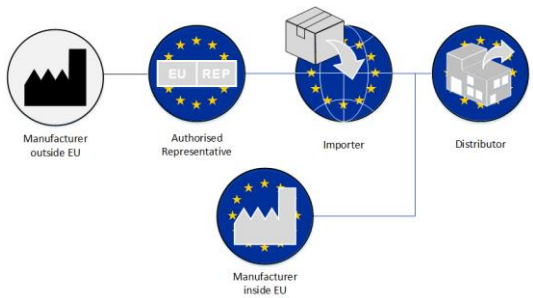
Takeaways from the MDR certification

Stage 2 on-site audit

Special considerations

- Outsourced processes, including distributors, importer and authorised representative.
- A formal management sign-off of the completion of the MDR implementation.
- A justification of the level of liability insurance that is sufficient based on product risk classes.



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Takeaways from the MDR certification

Stage 2 on-site audit

Recommendations

- Use internal audits as evidence of compliance and as basis for the formal management sign-off of the completion of the MDR implementation.
- Prepare a presentation and walkthrough of the processes of the largest changes, i.e. PMS, Clinical evaluation and Clinical investigation.
- Be prepared to motivate your interpretations and adaptations during the audit.

Caveat

The upcoming audits may be tougher, as there will be clarifications and guidance released from the commission and the Notified Body will be more experienced.

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Questions?

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Getinge is a leading global provider of innovative solutions for operating rooms, intensive-care units, hospital wards, sterilization departments, elderly care and for life science companies and institutions. With a genuine passion for life we build quality and safety into every system. Our unique value proposition mirrors the continuum of care, enhancing efficiency throughout the clinical pathway. Based on our first-hand experience and close partnerships, we are able to exceed expectations from customers – improving the every-day life for people, today and tomorrow.

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