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

Main challenges with EU MDR

March 31th, 2022

Senior Advisor
Corporate Regulatory Affairs
Karl-Yngve Keck

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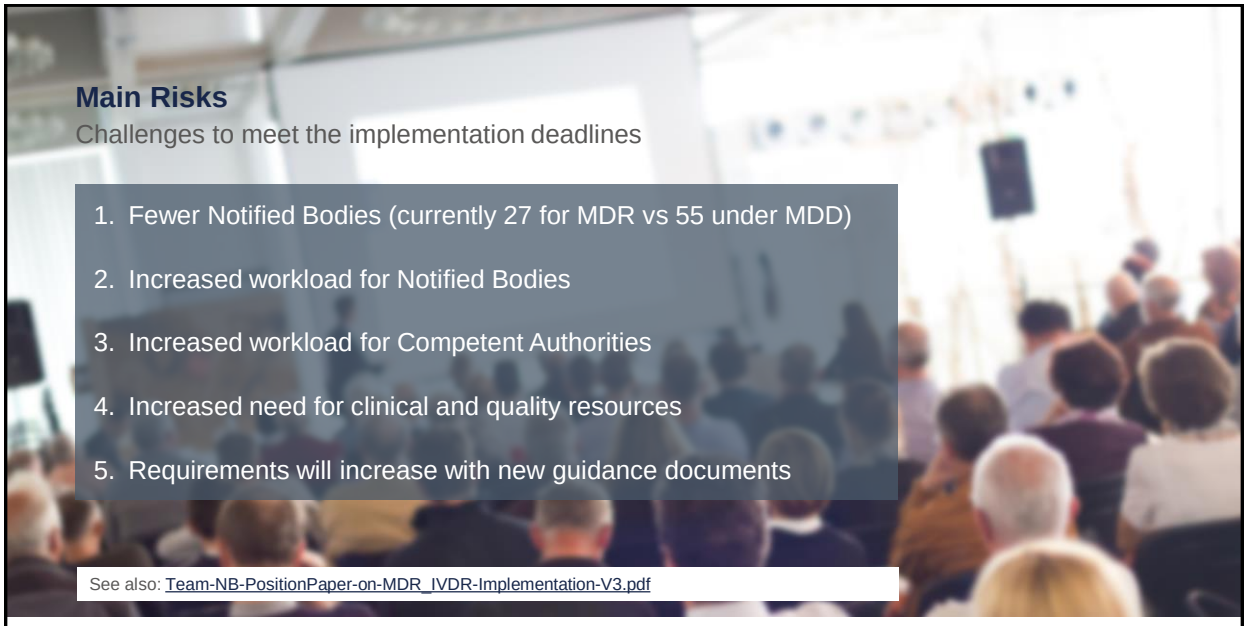

Main Risks

Challenges to meet the implementation deadlines

1. Fewer Notified Bodies (currently 27 for MDR vs 55 under MDD)
2. Increased workload for Notified Bodies
3. Increased workload for Competent Authorities
4. Increased need for clinical and quality resources
5. Requirements will increase with new guidance documents

See also: Team-NB-PositionPaper-on-MDR_IVDR-Implementation-V3.pdf

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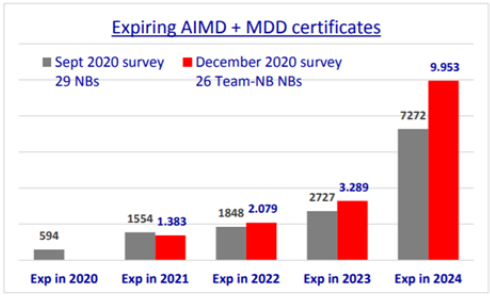
Main challenges with EU MDR

Increased workload for NB

- **Transition process form directives to regulations**

We can see in the next graph that only 1% of MDR certificates has been issued.

Applications represent 10% of MDD and AIMD certifications. Most of them are in the certification process. Some of them being at the final step and awaiting permission to perform the initial certification audit.



Source: https://www.team-nb.org/wp-content/uploads/2021/04/Team-NB-MD-Sector-Survey-PressRelease-20210414.pdf

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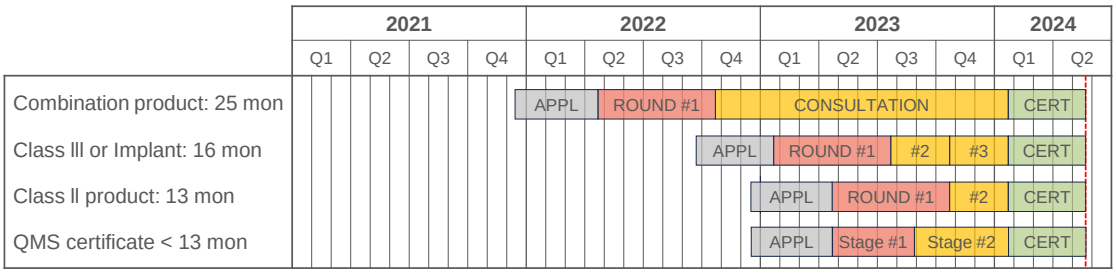
Main challenges with EU MDR

Increased time to marked due to increased times for QMS and product certifications



Application to start review
Review Round #1
Round #2/#3/Consultation
Certification

Note: Data based on times from several of the larger Notified Bodies

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Main challenges with EU MDR

Increased time to marked due to increased times for QMS and product certifications

Process steps	Drug consultation	Class III	Class IIa, IIb
Application to start of review	4 months	4 months	4 months
Review Round 1	6 months	6 months	6 months
Round 2 / Consultation	15 months	3 months	3 months
Round 3	N/A	3 months	N/A
Certification	4 months	4 months	4 months
Total time from TD submission	25 months	16 months	13 months

Note: Data based on times from several of the larger Notified Bodies

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Main challenges with EU MDR

Last time to apply and submit TD to meet 2020-05-26 deadline

Type of submission	Last day for application	Last day for TD submission
Combination product	2021-12-15	2022-04-26
Class III or Implant	2022-09-26	2023-01-26
Class II products	2022-12-15	2023-04-26
QMS certificate	2022-12-15	N/A

Note: Data based on times from several of the larger Notified Bodies

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Main challenges with EU MDR

Increased NB costs for MDR vs MDD

Type of Activity	Price per hour	Increased time*	Increased cost*
ISO 13485 certification	+ 0%	+ 0%	+ 0%
MDR audit	+ 30%	+ 10%	+ 33%
MDSAP and MDR audit	+ 20%	+ 10%	+ 22%
TD review per product	+ 40%	+ 25%	+ 50%

*Depends on quality of documentation and handling of findings

Note: Data based on times from several of the larger Notified Bodies

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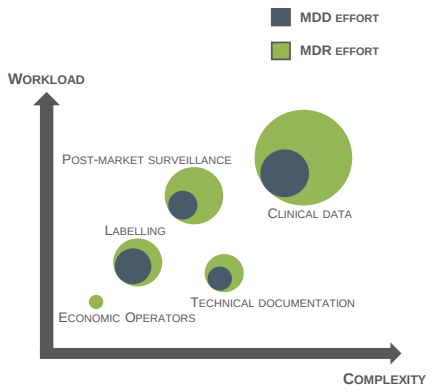
Main challenges with EU MDR

Increased workload between MDD and MDR



Workload per discipline:

- 25% R&D
- 25% RA/QA
- 10% Clinical
- 40% Clinical studies

- Clinical studies mainly related to class III and implantable products

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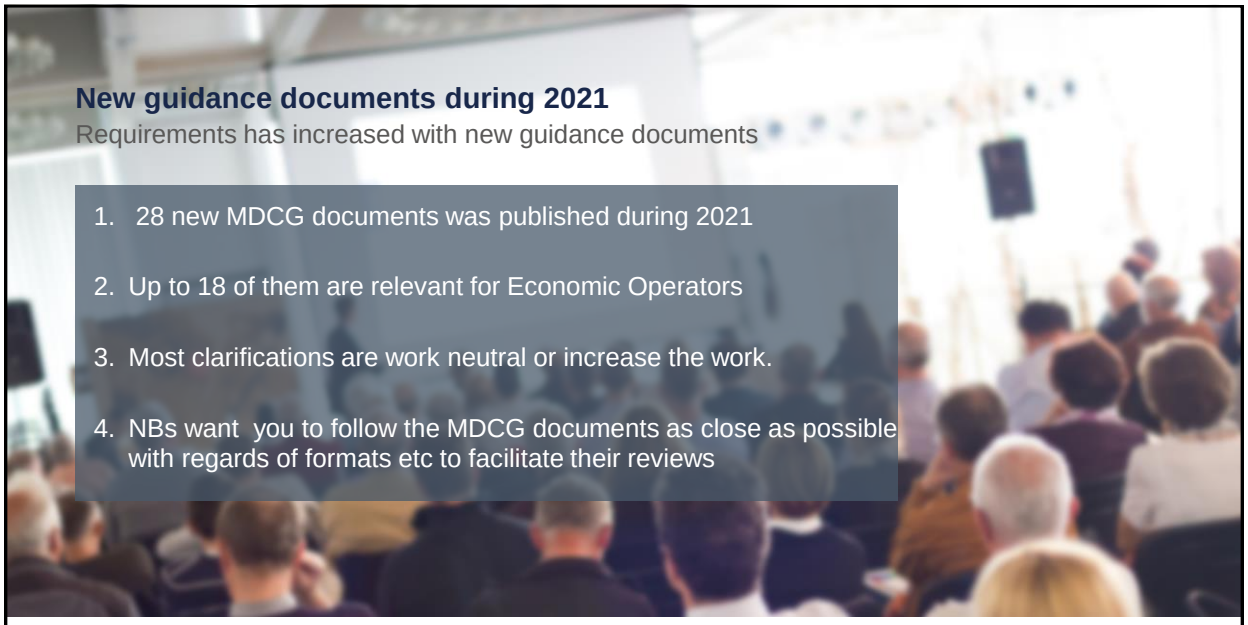

New guidance documents during 2021

Requirements has increased with new guidance documents

1. 28 new MDCG documents was published during 2021
2. Up to 18 of them are relevant for Economic Operators
3. Most clarifications are work neutral or increase the work.
4. NBs want you to follow the MDCG documents as close as possible with regards of formats etc to facilitate their reviews

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New guidance documents during 2021 - Highlights

Requirements has increased with new guidance documents

MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2021-13	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
MDCG 2021-23	Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4)
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2021-26	Questions and Answers on repackaging & relabelling activities under Article 16
MDCG 2021-27	Questions and Answers on Articles 13 & 14

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Summary

Time is of essence

In order to have class II and class Ix products CE-marked in time my recommendation is to:

1. April 2022 – Establish contact with NB
2. August 2022 (3 months + vacation)
   a) Confirm product codes
   b) That the NB supports the product codes
   c) Establish an overall submission plan
3. 15 December 2022 – last day to submit applications for all products

If you have problems meeting these deadlines, you should consider which part of your product portfolio to prioritize.

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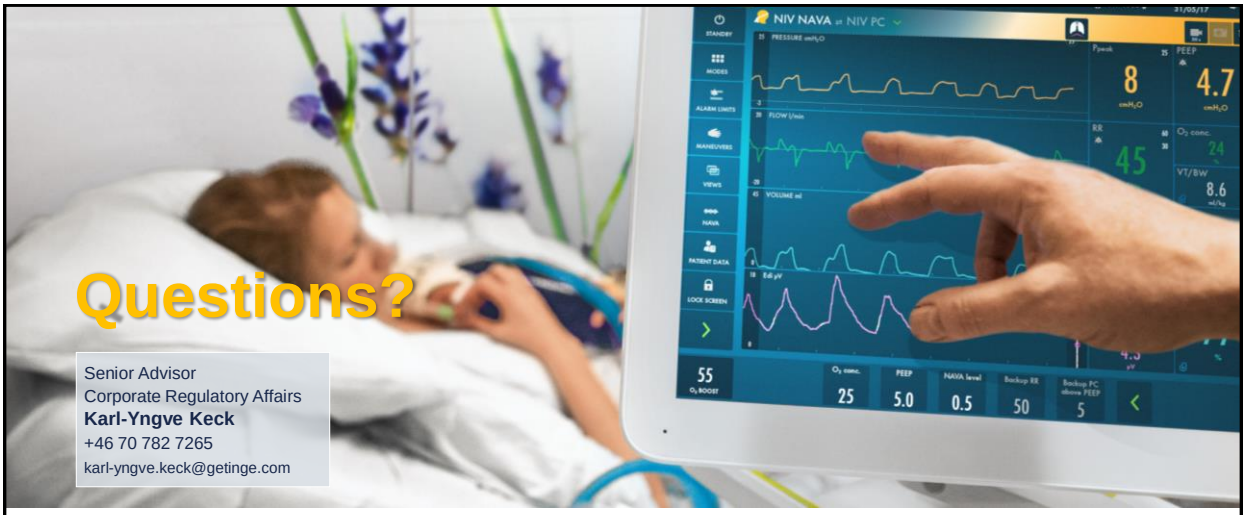

Questions?

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