Kapstone medical

Preparing Your Technical Documentation Under MDR

Proven Tips & Techniques

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greenlight guru

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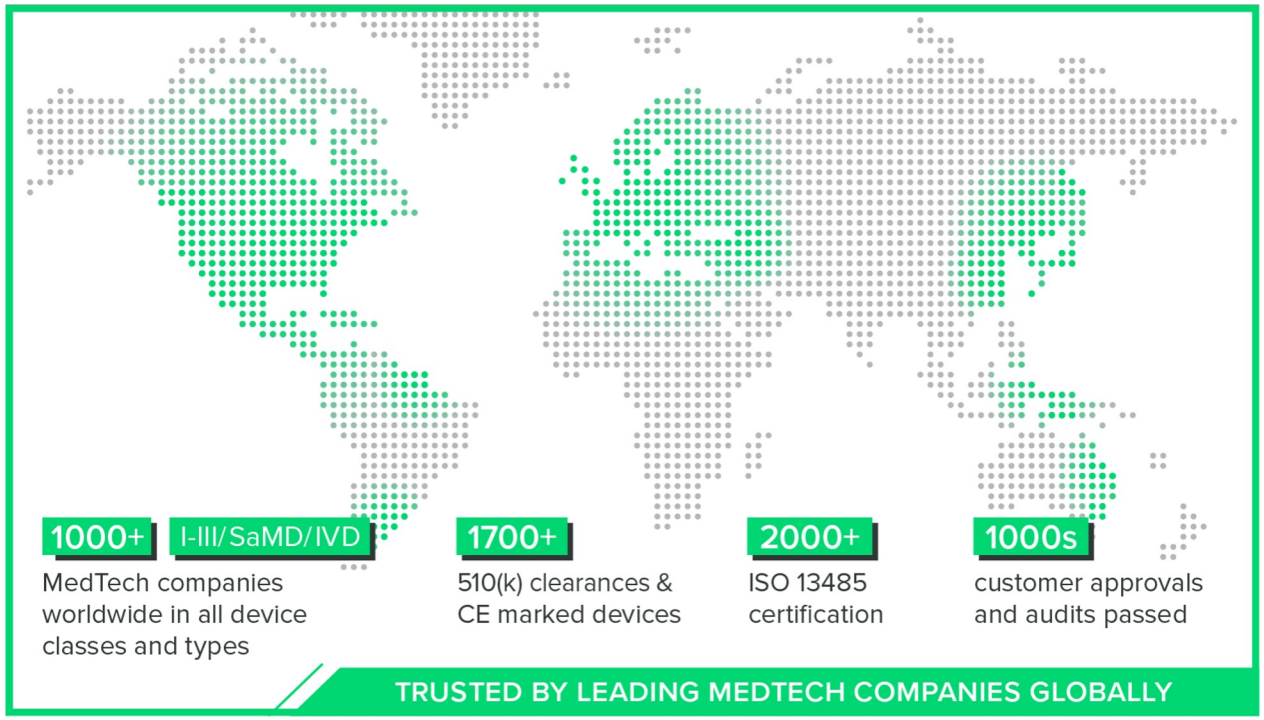

"Best QMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive, and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."

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"Demystifying QMS and Regulatory Requirements"

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"Makes your QMS Simple and Effective"

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In this Webinar….

- Understand the current requirements under EU MDR
- Identify the tools made available to industry
- Understand the areas of focus for your technical documentation and QMS
- Learn tips to ensure clear communication with your Notified Body

EU Medical Device Regulations (2017/745)

- What is the EU MDR 2017/745?
  - Life-cycle approach to regulation of medical devices (pre-, post-market)
  - Mandate for Unique Device Identification
  - Increased focus on Clinical data and Postmarket Surveillance (including PMCF)
- Implementing Acts
- Common Specifications
- Current topics:
  - Notified body capacity
  - Extension of certification under MDD for eligible legacy devices

Regulation 2023/607

- Gives manufacturers more time to carry out the conformity assessment, in accordance with the MDR, of devices covered by a certificate, or a declaration of conformity issued in accordance with the MDD, so called legacy devices.
- No "sell-off" date
- The following devices are eligible for the extended transitional period:
  - devices which are class I devices under MDD, for which an EC declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body,
  - devices covered by a valid EC certificate issued in accordance with the MDD prior to 26 May 2021.
- The extension of the transitional period beyond 26 May 2024 only applies if the conditions laid down in Article 120(3c) MDR are fulfilled.

Regulation 2023/607

- Review classification according to MDR to evaluate up-classification.
- Demonstrate compliance to MDR 10(9) (QMS)
- Continue compliance with MDD, and Article 120
- No significant changes in design and intended purpose
- Before 26 May 2024, lodge a formal application for conformity assessment and before 26 September 2024, sign a written agreement.
  - The application must clearly identify the manufacturer and the devices covered by the application.
  - A timeline for possible submission of the individual technical documentation and any other relevant information must be provided.

Regulation 2023/607

- Extended timelines:
  - 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
  - 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function
  - 31 December 2028, for devices MDD did not require involvement of a NB, a DoC was drawn up prior to 26 May2021, but MDR requires involvement of NB

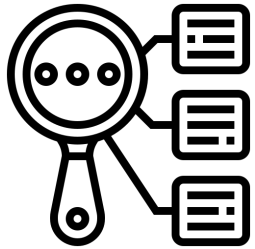
MDCG Guidance Documents

- Medical Device Coordination Group (MDCG)
- Guidance in application of Regulation (EU) 2017/745 on medical devices (MDR)
- The documents are not legally binding. They present a common understanding of how the MDR should be applied in practice aiming at an effective and harmonized implementation of the legislation.
- https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
- Examples:
  - MDCG 2022-14: MDCG Position Paper - Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs

Team-NB Position Papers

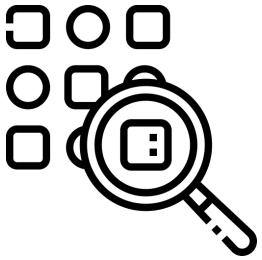
- The European Association for Medical Devices of Notified Bodies
  - https://www.team-nb.org/
  - Formed in 2001
  - Pursuing transparency for notified bodies in Europe
  - Active involvement and support on the implementation of the new Medical Device Regulation, e.g., guidance documents.
  - Support to notified bodies, through guidance documents, to ensure a standard is achieved by notified bodies
- Example of a Position paper:
  - *Team-NB-PositionPaper-BPG-TechnicalDocEUMDR-2017-745-V2-20230419:* Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 2017/745

MDR Technical Documentation Review



Classification

Dictates the conformity assessment route, and therefore the regulatory scrutiny

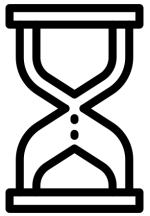


Sampling

Annex IX, Section 2.3: sampling of technical documentation taking the following into account:

- Risks associated with the intended use of the device
- Novelty of the technology
- Complexity of the manufacturing process
- Results of any previous relevant assessments
- Range and classes of devices produced
- Available postmarket surveillance information
- Prevalence and volume of distribution into Europe for a product type

MDR Technical Documentation Review



Timing of Review

Can occur as part of obtaining a CE certificate or during a routine QMS audit

General Safety & Performance Requirements

Assess product technical documentation safety and performance requirements: Annex I.

Preclinical and Clinical Testing

Take into account requirements related to preclinical testing and clinical evaluations.

Addressing Challenges(MDCG 2022-14)

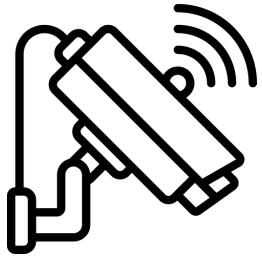
Increase Notified Bodies capacities… elements that impact Manufacturers

Hybrid Audits

Use of hybrid audits would contribute to conducting the conformity assessment in a timely and efficient manner

Evidence

Leveraging evidence, or components thereof, from previous assessments conducted with regard to requirements under the Directives

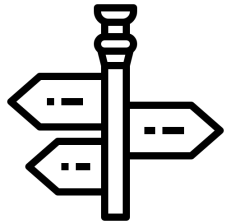


Surveillance

'Appropriate surveillance' of legacy devices

Addressing Challenges(MDCG 2022-14)

Increase Notified Bodies capacities… elements that impact Manufacturers



Guidance

Economic operators and notified bodies should be allowed flexibility as to how to demonstrate compliance with legal requirements

Access to Notified Bodies …

Fees

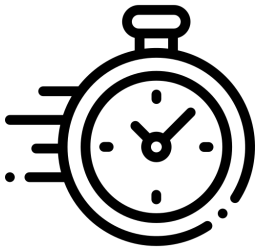
Obligation to make their standard fees publicly available, considering the interests of SMEs in relation to fees.

Capacity

Develop schemes in order to allocate capacity for SME manufacturers and first-time applicants and ensure access of SMEs and first-time applicants to notified bodies for conformity assessment.

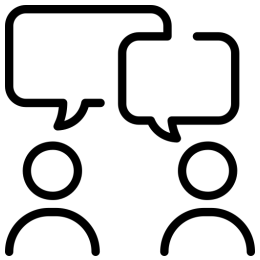
Addressing Challenges(MDCG 2022-14)

Increase preparedness of manufacturers…



Timeliness

Manufacturers need to ensure timely compliance with MDR requirements.



Dialogue

Organize structured dialogues before and during the conformity assessment process where this is useful to enhance the efficiency and predictability of the conformity assessment process.

Education

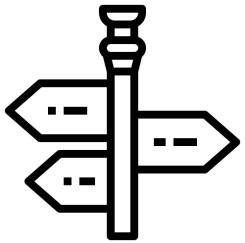
Communication with manufacturers by means of webinars, workshops, targeted feedback and informative sessions

Addressing Challenges(MDCG 2022-14)

Other actions facilitating transition to MDR/IVDR and/or avoiding shortage of devices…

Complexity and Pragmaticism

Complexity of conformity assessments should be reduced, and more pragmatism ensured



Guidance

Additional guidance for practical application of Article 61 MDR (clinical evaluation) and to make appropriate use of MDCG guidance on clinical evidence for legacy devices11 and clinical evaluation – equivalency

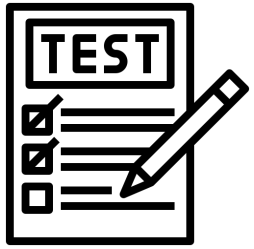
MDR Technical Documentation Focus

Clinical Data

The word "clinical" is mentioned 684 times in MDR vs 48 in MDD. Intense scrutiny of your clinical evidence and supporting clinical data of the device

Intended Purpose, Indications for Use, and Claims

Notified bodies will be looking at your specific claims and how they are supported by clinical data.



Performance Testing

Notified Bodies want to see more emphasis on product validation measuring performance in an actual use environment.

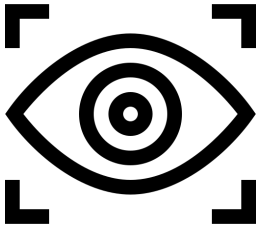
MDR Technical Documentation Focus

Benefit-Risk Analysis

The EU MDR (and ISO 14971:2019) now stress the importance of measuring benefits, not just risks.

Residual Risk

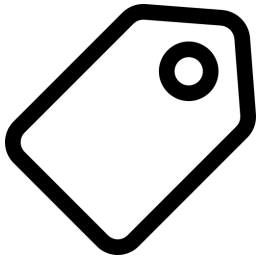
ISO 14971:2019 and the EU MDR also emphasize the need to reduce risk to the lowest levels practicable. The Notified Body will be looking into your risk analysis more closely, especially your assessment of residual risk



Postmarket Surveillance

Demonstrates risk management as an on-going process

MDR Technical Documentation Focus



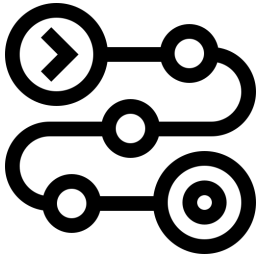
Labeling

The Notified Body will evaluate Instructions for Use in light of stated claims and intended purpose.

MDR Technical Documentation Tips

Completeness

Ensure your submission is complete.
Incomplete or inconsistent description of devices.
Leads to delays in starting or additional questions and you only have 3 rounds of questions – use it wisely



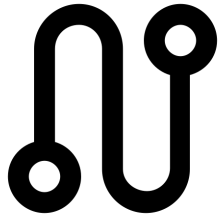
Structure

All electronic submissions – use bookmarks or hyperlinks
Let the auditor find what they're looking for easily

Communication

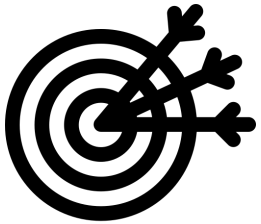
Initiate conversation with the notified body before an application is lodged.

MDR Technical Documentation Tips



Traceability

Ensure all requirements are traceable to evidence of verification and validation.



Consistency

Ensure that there is consistency across supporting documents.

No Repetition

Avoid repetition.

MDR Technical Documentation Tips

Justification

Ensure that justifications are scientific. Whether it be sample sizes, complaints rates, corrective action, deviations from test protocols, test failures, etc., always provide a scientific rationale. Don't wait to be asked.

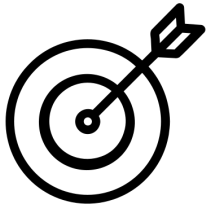
Imperfections

Address the imperfections. Confront the imperfections, provide a clear history, and provide rationales and justifications for discrepancies. Use PMS data as a safety net, and commit to more rigorous PMCF

Significant Issues

Focus on the significant issues – clinical data, risk management, V&V.

MDR Technical Documentation Tips

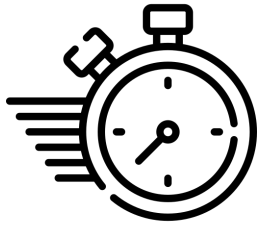


Claims

Don’t make unsubstantiated claims.

Self Audit

Audit your technical documentation before submission to the Notified Body.



Responsiveness

Be responsive to your Notified Body.

Questions?

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