



Best-Practice Guidance for Manufacturers Preparing MDR Notified Body Submissions

This document provides key references to assist you in preparing technical documentation (TD) for submission to SGS Belgium NV (NB 1639) for conformity assessment according to the Medical Device Regulation (EU MDR 2017/745). We recommend using the published MDCG templates together with the relevant best-practice guidance when preparing your technical documentation, as this facilitates the review process, improve predictability, and reduce queries arising from missing or unclear information.

List of relevant guidance:

1. Technical Documentation (TD)

Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of the Medical Device Regulation (EU) 2017/745:

[Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V3-20250409.pdf](#)

2. Clinical Evaluation Plan (CEP)

MDR Annex XIV Part A Paragraph (1)(a), for new devices and MDCG 2020-06 Appendix II for Legacy Devices:

[DocsRoom - European Commission](#)

3. Clinical Evaluation Report (CER)

MEDDEV 2.7.1 Rev 4 Appendix A9, Proposed Table of Contents of the CER When Equivalence is Claimed: MDCG 2020-5 Annex I Equivalence Table:

[Guidance - MDCG endorsed documents and other guidance - Public Health](#)

4. Post-Market Clinical Follow-up (PMCF)

MDCG2020-7 PMCF Plan Template; MDCG2020-8 PMCF Evaluation Report Template:

[Guidance - MDCG endorsed documents and other guidance - Public Health](#)

5. Periodic Safety Update Report (PSUR)

MDCG 2022-21 PSUR Template:

[Guidance - MDCG endorsed documents and other guidance - Public Health](#)

6. Summary of Safety and Clinical Performance (SSCP)

MDCG2019-9 Rev1 Appendix: Template for the SSCP:

[Guidance - MDCG endorsed documents and other guidance - Public Health](#)

7. Harmonized Standards for Medical Devices

[Medical devices - Internal Market, Industry, Entrepreneurship and SMEs](#)

Please also consult the MDR Technical Documentation Request Form, available on the [SGS EU Medical Device Regulation \(MDR\) Information Center](#). This form includes a detailed checklist specifying the required information and its expected location within your technical documentation.

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When you need to be sure

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