

Best Practice Reference List for Preparing MDR Technical Documentation

Guidance for Manufacturers

This document provides the references to assist you in preparing technical documentation (TD) for submission to SGS Belgium NV (NB 1639) for conformity assessment, according to Medical Device Regulation (EU MDR 2017/745). We suggest using published MDCG templates and the best practice guidance to prepare your TD before submission, as it will facilitate the TD review process, increasing predictability while reducing queries due to missing or unclear information.

List of guidance:

1. Technical Documentation (TD)

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

<https://www.team-nb.org/wp-content/uploads/2025/01/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V2-20230419.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:

<https://ec.europa.eu/docsroom/documents/40904>

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:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec4

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

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

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec4

5. Periodic Safety Update Report (PSUR)

MDCG 2022-21 PSUR Template:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec16

6. Summary of Safety and Clinical Performance (SSCP)

MDCG2019-9 Rev1 Appendix: Template for the SSCP:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec4

7. Harmonized Standards for Medical Devices

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/medical-devices_en

Please also refer to the **MDR Technical Documentation Request Form**, available on the SGS website:

<https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center>. It provides a checklist for the location of the required information within your TD.