

## 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:

[Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V3-20250409.pdf](https://ec.europa.eu/docsroom/documents/40904)

#### 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](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](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](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](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](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.

SGS Belgium

NV Registered office: Noorderlaan 87 B-2030 Antwerp t +32 (0)3 545 44 00 f +32 (0)3 545 44 99 www.sgs.be

VAT: BE

0404.882.750 Register of  
legal entity: Antwerp, Department of Antwerp IBAN: BE 87 5701 3412 5594 BIC: CITIBEBX

Behoudens andersluidende overeenkomst worden alle opdrachten uitgevoerd op basis van onze algemene voorwaarden. Op eenvoudig verzoek worden deze voorwaarden opnieuw aan u toegezonden.  
A moins qu'il ait été convenu autrement, toutes les commandes seront exécutées sur base de nos conditions générales. Ces conditions vous seront de nouveau envoyées sur simple demande.  
Unless otherwise agreed, all orders are executed in accordance with our general conditions. Upon simple request the conditions will again be sent to you.