MDCG 2026-7

Guidance on Technical Documentation Assessment Report and PSUR evaluation for Eudamed (MDR)

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1 LIST OF ACRONYMS

CEAR: Clinical Evaluation Assessment Report

CECP: Clinical Evaluation Consultation Procedure

CEP: Clinical Evaluation Plan

CER: Clinical Evaluation Report

DoC: Declaration of Conformity

Eudamed: European database on medical devices

GSPRs: General Safety and Performance Requirements

IFU: Instructions for Use

MDR: Medical Device Regulation (Regulation (EU) 2017/745 on medical devices)

NB: Notified Body

NC: Non-conformity

PMCF: Post-Market Clinical Follow-up

PMS: Post-Market Surveillance

PSUR: Periodic Safety Update Report

Q&A: Questions and Answers

QMS: Quality Management System

SER: Summary Evaluation Report

TD: Technical Documentation

TDAR: Technical Documentation Assessment Report

2 INTRODUCTION

This guidance describes the expected minimum set of elements to be documented in technical documentation assessment reports (TDARs) written by the notified body (NB) and provided to the manufacturer. In the Appendix, a PSUR (Periodic Safety Update Report) evaluation template is provided for cases when NBs have to upload their evaluation as an attachment in Eudamed.

3 SCOPE

This guidance applies to the NBs' assessments of the manufacturer's technical documentation (TD) that is to be drawn up in accordance with Annexes II and III of MDR. The TDAR is an essential part of conformity assessment procedures described in Annex IX Sections 4 and 5 and Annex X Section 3. It also applies to assessments on a sampling basis for class IIa/IIb devices in accordance with Annex IX Sections 2.3 and 3.5, and Section 10 of Annex XI(A), as applicable. Aspects related to the technical documentation assessment are also laid down in Sections 4.5.1, 4.5.3, 4.5.4 and other relevant

Sections of Annex VII as well as in Annex IX. NBs PSUR evaluation content according to Article 86(2) of the MDR is also provided.

4 OBJECTIVES OF A TDAR

The TDAR is compiled by the NB to document the outcome of its assessment of a manufacturer's TD. Its use is not limited to initial certification and to the assessment of the TD on a sampling basis. The guidance could be used when recording any assessment of manufacturer changes to the TD which is carried out by the NB after initial certification, including possible changes assessed during surveillance or re-certification activities.

Technical documentation includes the elements described in Annexes II and III of the MDR and evidence of compliance with the General Safety and Performance Requirements (Annex I) applicable to the relevant device(s). This includes, among others, clinical data and additional information required in specific cases, such as where a medicinal substance is incorporated or integral to the device, where tissues or cells of human or animal origin, or their derivatives, are utilised, or where the device is placed on the market in a sterile condition or has a measuring function. A more comprehensive description of its content is detailed in section 5.

The TDAR should focus on the outcomes of the assessment performed in all areas and aspects described in Annex II and III of MDR, as well as demonstration of fulfilment of the GSPRs according to Annex I. The TDAR must conclude with a clear recommendation for the final review and decision-making process in advance of initial certification being issued by the NB, or for maintaining certification during certification cycle, describing whether the respective TD fulfils the applicable MDR requirements.

The benefit of the TDAR for a NB will be to ensure that final reviewers and decision makers have a concise but comprehensive summary report that will allow them to accomplish their tasks. Designating and competent authorities may also use the TDAR as part of their monitoring and surveillance activities.

The conclusion and recommendation for the whole conformity assessment project[1] are not expected to be documented in the TDAR as further activities/reports need to be considered according to the conformity assessment procedure, e.g.:

- in case of assessments of TDs on a sampling basis for class IIa/IIb devices in accordance with Annex IX Sections 2.3 and 3.5 and Section 10 of Annex XI(A), beside the TDARs and associated CEARs (Clinical Evaluation Assessment Reports) the outcome of QMS audit(s);
- in case of assessments according to MDR Annex IX Section 4, additional results of specific conformity assessment activities (e.g., CECP or other consultations);
- in case of assessments according to MDR Annex X Section 3, beside the TDAR/CEAR the individual arrangements/reports of the type-examinations.

[1] MDR Annex VII, section 4.4, 2nd subparagraph, and 4.5.1, first indent.

The TDAR should be part of the NB's existing internal procedures and conformity assessment documents (e.g., internal conformity assessment report templates, queries, sub-reports and correspondence) and should be incorporated into the NB's quality management system (QMS).

5 MINIMUM CONTENT OF TDAR

The minimum content of the TDAR includes all elements described in Annexes II and III of MDR. Each requirement must be considered and accounted for within the TDAR.

Each requirement in Annexes II and III need to be addressed within the TDAR with clear statements on the outcome of the NB's assessment and with clear conclusions indicating whether the manufacturer has met each requirement. The outcome reported in the TDAR should indicate any areas where challenges have been identified (e.g., multiple rounds of review or queries between the NB and the manufacturer, and areas where compliance was not easily demonstrated)[2].

It is understood that all documentation associated with the assessment performed by the notified body, including the complete audit trail, all queries, associated follow-ups and assessment notes documented by the NB will not necessarily be contained in the TDAR.

A summary section should be included to document the outcome of the overall assessment and conclusions drawn, following verification of the manufacturer's conformity with the requirements of the MDR. It should be clearly documented whether the manufacturer ultimately was able to demonstrate compliance with the MDR or whether there are areas with remaining (minor) non-conformities (NCs) that require further follow-up by the NB post-certification, e.g., if a certificate with condition is recommended. In all cases, the TDAR needs to contain a clear recommendation for the final review and decision-making process. In all cases, the TDAR needs to contain a clear recommendation for the first review and decision-making process. The NB's documented assessments of the TDAR should allow demonstration of its critical thorough review and assessment of the manufacturer's TD with critical conclusion and, where necessary, non-conformities regarding the applicable requirements.

All fields and sections of the TDAR should be completed appropriately and there should not be an over reliance on copying and pasting of manufacturer's technical data, text or images from the manufacturer's TD into the TDAR to indicate compliance. The NB itself should document its rationale and conclusions as to why the manufacturer's TD is compliant with the MDR.

All sub-reports and other documents of relevance to the overall conformity assessment activities should be referenced in the TDAR (i.e., reference, revision and date, and specific section in case of large documents). When, as part of conformity assessment activities performed by the NB, specific additional procedures are needed and assessments under those procedures are not included in the TDAR, associated reports need to be referenced in the TDAR. Examples of sub-reports include the CEAR and summary evaluation report (SER). Sub-reports could also be other reports generated by the NB when reviewing aspects such as sterilisation, software or measuring function.

[2] In accordance with MDCG 2020-13, it is important to note that the TDAR may not necessarily contain comprehensive information regarding the non-conformities/deficiencies, which were raised by the notified body during the course of the assessment.

Examples of best practice in the TDAR:

- Evidence that demonstrates that the NB carried out a critical, thorough and robust review by providing a written, comprehensive and well-justified assessment covering all applicable aspects.
- Identification of the manufacturer's relevant TD (documents or folders and/or relevant sections, as appropriate) in each section of the TDAR.
- A clear indication if any NCs have been raised and in which areas NCs were found during the assessment.
- Reference to NC reports, list of Q&A addressed to the manufacturer, etc., where applicable.

Examples of insufficient practices in the TDAR:

- Extensive use of copy and paste or snapshots from the manufacturer's TD. *It is considered unnecessary documentary overload compromising clear and complete assessment documentation*.
- Assessments based on a checklist outcome, without further documented evaluation comments from the product reviewer(s). *Written and justified critical assessment is missing, not allowing rationale and acceptance criteria to be complete and understood*.
- Including long lists (of folders/subfolders, documents, warnings and cautions etc.) that do not add value to the report. *It is considered unnecessary documentary overload with inappropriate assessment writing and traceability of the assessment*.
- Use of "pass/fail" criteria without definition or reference to clear and unambiguous acceptance criteria (using Harmonised Standards or Common Specifications for example), whether in binary queries or descriptive sections. *Written and justified critical assessment is missing, not allowing rationale and acceptance criteria to be complete and understood*.
- Assessment restricted only to the positive outcome from the last/most recent version of manufacturer's TD without clear indication if any NCs have been raised, or in which areas NCs were found in the course of assessment. No mention of which sections have been revised, without reference to NC reports, list of Q&A addressed to the manufacturer, etc. *Lack of traceability in the documentation (both reports and assessment outcomes) do not allow appropriate identification of areas of concern raised during the assessment*.
- No clear identification of topics/actions to be followed up by the NB. Use of generic wording such as "progress on gaining additional data will be followed up in the course of regular audits". *Lack of details and insufficient traceability of topics/actions to be followed up and/or related documentation*.
- Insufficient identification/referencing of manufacturer's documentation with, for example, the use of unspecific cross-reference such as "see manufacturer's TD". *Lack of traceability for the location (including specific section where relevant) and identification of the reports, sub-reports and other documents of relevance to the overall conformity assessment activities*.
- Insufficient justification for non-applicability of sections of the TDAR. *Written and justified critical assessment is insufficient, not allowing rationale and acceptance criteria to be complete and understood*.

NB personnel that are authorised and allocated for assessments, including external experts as well as personnel under training or supervision, should be identifiable to allow traceability between sections

of the TDAR and NB personnel involved in the assessments. The NB may wish to develop a system for personnel identification (e.g., employee coding system) that would also be used to ensure anonymity for personnel involved in the assessments when the TDAR is shared externally with the manufacturer.

The TDAR should be signed off by qualified personnel within the NB. When making the TDAR available to third parties (except to the authorities responsible for NBs, competent authorities for medical devices in the Member States or the Commission), the NB should treat the personal data within it as per its procedures for the management of personal data, in compliance with Regulation (EU) 2016/679 General Data Protection Regulation.

The TDAR, along with the CEAR, must be provided to the manufacturer of the device(s) that was subject to the conformity assessment application, at the end of the process.

6 GENERAL CONSIDERATIONS

The notified body is required to ensure that

- **all steps** of the conformity assessment are documented so that the
- **conclusions** of its own conformity assessment activity are clear and
- it is clearly documented whether the manufacturer was able to demonstrate **the conformity with the applicable requirements** of the MDR for the device(s) under assessment, especially the applicable GSPRs set out in Annex I and the technical documentation requirements set out in Annexes II and III.

To illustrate all steps clearly, the NB should document in each section of the TDAR the objective evidence and/or references to manufacturer's TD that were subject to the particular assessment step as well as a statement on its assessment.

For the TD requirements set out in point (c) of Section 6.1 of Annex II, referring to the CEP/CER, and point (d), referring to PMCF, and Annex III, referring to PMS, the NB may refer to the CEAR.

Both TDAR and CEAR need to contain information necessary for an unambiguous identification of the device(s) for which the technical documentation was assessed (details see section 5).

If the NB's assessment information is covered by sub-reports, NC reports etc., the NB should make a clear reference to them.

In case of objective evidence which was assessed in a previous TD assessment, and the result of this previous assessment is still valid considering the state of the art and applicable for the ongoing assessment, NBs might give an unambiguous reference to its previous report. See also MDCG 2019-6 Q&A IV.13 regarding leveraging of evidence.

As manufacturer's TD is linked to its QMS and depending on the NB's planning on the conduct of conformity assessment activities, some aspects of Annex I, II or III might already be assessed during the QMS audit after or prior to the TD assessment. These include process-related elements, such as (non-exhaustive list of examples): control of critical subcontractors and crucial suppliers, design control, translation of the IFU (Instructions for Use) and DoC (Declaration of Conformity), upload of the IFU to the manufacturer's website in compliance with Article 9 of Regulation (EU) 2021/2226,

and vigilance. These activities may be documented in the NB's audit report to which the TDAR should refer.

Some additional items that are not explicitly mentioned in Annex I, II or III can be part of the TDAR, such as CE marking in accordance with Article 20 and Annex V, and compliance of the DoC with Article 19 and Annex IV. Additional items that are relevant to specific horizontal MDR codes can also be included.

While compliance with standards generally is not compulsory, compliance to GSPRs require a demonstration of the state of the art. Where standards are not claimed by the manufacturer, product reviewers have to assess and document manufacturer's TD suitability (including for example gap analysis or rationales) in comparison with state of the art (see last paragraph of Section 4.5.1 in Annex VII).

7 PSUR EVALUATION

For the devices mentioned in Article 86(2) of the MDR, PSURs are to be uploaded by the manufacturer to Eudamed (when operational). The NB is required to review the PSUR and, in this case, add its evaluation to Eudamed specific data entry fields with details of any action taken by the NB, regardless of the outcome of the review. While the upload to Eudamed of the PSUR evaluation *as an attachment document* is optional when NB agrees to the manufacturer's PSUR conclusions (in addition to information already documented in Eudamed specific data entry fields), Eudamed requires the upload in the case where NB does not agree to manufacturer's PSUR conclusions.

As the PSUR is part of an on-going post-market surveillance process requiring regular updates of the documents, traceability of NB assessment outcomes should focus on the comparison between the current PSUR(s) with the previous one(s). PSUR evaluation is not expected to require full manufacturer's TD assessment by the NB.

This PSUR evaluation by the NB is to be conducted in addition to PSUR review during assessments of the manufacturer's technical documentation on a sampling basis and/or changes assessed during surveillance or re-certification activities (see also section 3).

Template of the *PSUR evaluation* is presented in the Appendix of this guidance, providing the expected minimum set of elements to be documented. This template can be complemented by further information depending on NB QMS requirements. When assessing the PSUR provided by the manufacturer, the notified bodies' personnel should consider the assessment principles set out in this guidance. This template can also be used as a basis by NBs for other cases where an upload as an attached document to Eudamed is not required.

APPENDIX : PSUR EVALUATION TEMPLATE

PSUR evaluation content:

The following sections shall be used to record appropriate identification information.

1. **Manufacturer and certification information**
   - Manufacturer Single Registration Number
   - Manufacturer organisation name
   - Manufacturer address
   - Certificate number(s)
   - NB project reference (optional)
2. **Medical device information**
   - Leading device Basic UDI-DI
   - Leading device risk class
   - Leading device EMDN code
   - Other Basic UDI-DI(s)/Eudamed DI(s)
3. **PSUR information**
   - PSUR reference number
   - PSUR version
   - Data collection period covered
   - Date on which PSUR was received by NB
   - PSUR previous version and date

Notified Body conclusion(s) and action(s) taken

3.1. Information required by Article 86(1) points (a), (b) and (c):

Article 86(1)(a): Is there a change of the benefit-risk profile reported by the manufacturer?

☐ Yes: …… .....

☐ No.

Article 86(1)(b): Are the main finding(s) of the PMCF documented?

☐ Yes.

☐ No: …… .....

Article 86(1)(c): Are the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device documented?

☐ Yes.

☐ No: …… .....

3.2. Does the Notified Body agree with the manufacturer's PSUR conclusions?

☐ The Notified Body agrees with the manufacturer's PSUR conclusions.

☐ The Notified Body does not agree with the following manufacturer's PSUR conclusions (justification): .....
.....
.....
.....

3.3. Are any actions taken by the Notified Body?

☐ No actions required.

☐ Yes. Based on the evaluation, the following actions are taken: .....
.....
.....

4. Notified Body evaluation team and details

4.1. Notified body's personnel name(s), signature & date

[…]

4.2. Date of the PSUR evaluation

[…]