# Q&A

# MDR / IVDR

# Verification

by the
Authorized Representative
(AR) / (EC REP)

MDSS
Medical Device Safety Service

# How does the verification process look like?

The AR is legally required to “verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer” (see MDR/IVDR Article 11, 3(a)).

The declaration of conformity is covered by Annex IV; the technical documentation is covered by Annex II and Annex III. If the manufacturer mirrors its declaration/documentation with these Annexes, MDSS expects a fast verification process.

# How to prepare my technical documentation to facilitate the verification process?

According to Annex II, “the technical documentation […] shall be presented in a clear, organised, readily searchable and unambiguous manner”. MDSS made the experience that a clear structure will also facilitate the verification process.

Eventually, the technical documentation may use the same order and headlines for each chapter of the technical documentation as it is used in Annex II and III. Having one master file with basic information which then refers to other files (e.g., risk management report, clinical evaluation report) is also recommended.

# Are there requirements to the documentation, which are often overseen by manufacturers?

- The Basic UDI-DI has to be given on the Declaration of Conformity.
- Product names should be identical throughout the technical documentation and the Declaration of Conformity.
- The intended purpose has to be given on the Declaration of Conformity.
- The Declaration of Conformity must cover other CE marking legislations applicable to the device, most notably RoHS 2011/65/EU and PPE 2016/425.
- The date and place of issue have to be shown on the Declaration of Conformity.
- All classification rules have to be reviewed and the ones, which are not applicable, should be documented accordingly. It may not be sufficient to list only applicable rules.
- All chapters of Annex II shall be covered (especially chapters of Annex II.1 are often missing). It is recommended to include all chapters of Annex II and then write which ones are not applicable. Otherwise, in case of a missing chapter, it may be unclear, if the chapter was forgotten or is not applicable.

- The technical documentation has to include the complete sets of labels and instructions for use, not only samples.
- An identification that device is a medical device has to be shown on the label.
- The GSPR checklist should include “explanations as to why others do not apply”.
- Design & manufacturing information according to Annex II (3) is required.
- Benefit-risk analysis is required.
- A clinical evaluation plan is required.
- The clinical evaluation data is required.
- A clinical evaluation report is required.
- If a PMCF/PMPF is not applicable, a justification has to be provided.
- A PMS plan is required.

# Are useful documents or standards for specific parts of the Technical Documentation available?

Yes, the following standards may apply:

- Risk management – ISO 14971
- Clinical evaluation – ISO 14155
- PMS – ISO 20416
- QMS – ISO 13485

The below list shows available guidelines free of charge:

- Clinical evaluation:
  - MEDDEV 2.7/1
  - MDCG 2020-6 (Guidance on sufficient clinical evidence for legacy devices)
  - MDCG 2020-13 (assessment report template)
  - MDCG 2020-1 (clinical evaluation of software)
  - MDCG 2020-5 (equivalence)
- PMCF:
  - MDCG 2020-7 (plan)
  - MDCG 2020-8 (report)
- Other:
  - MDCG 2019-15 (Guidance notes for manufacturers of class I medical devices)
  - MDCG 2020-2 (Class I transitional provisions under Article 120 (3 and 4)
  - MDCG 2019-11 (Qualification and classification of software)

The abovementioned MDCG guidelines (and more) can be downloaded here:

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

Some MDCG documents are in preparation and it is recommended to periodically check the website for new revisions/other topics addressed.