



Guidance for IVDR Technical Documentation Submissions

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1 Introduction

Manufacturers shall ensure the conformity of in vitro diagnostic medical devices being placed on the European market in accordance with the applicable requirements of (EU) 2017/746 In Vitro Diagnostic Medical Devices Regulation (IVDR).

Depending on the classification of the device and the conformity assessment route chosen, one or more Technical Documentation(s) need to be assessed by a Notified Body. This Technical Documentation submission guidance is aligned to the requirements of (EU) 2017/246 In Vitro Diagnostic Medical Devices Regulation (IVDR), described in detail in Annexes II and III.

TIPS TO GET STARTED AND COMMON FEEDBACK

TÜV Rheinland and medical device manufacturers are keen to streamline and speed up the assessment of the Technical Documentation as part of initial applications, during surveillance activities, substantial change notifications, renewal applications etc. and reducing time to certification. The most common reasons for delays in Technical Documentation assessments are:

- Incomplete Technical Documentation (TD) – not all the information needed for the assessment was submitted by the manufacturer from the beginning.
- Unsuitable Technical Documentation structure – the documentation and information is presented in a manner that makes it difficult for TÜV Rheinland to verify the product in question complies with the regulation, especially with the General Safety and Performance Requirements (GSPRs) of Annex I.
- Inaccurate references in the Technical Documentation – References are made to general TD sections (such as “Analytical Performance Data” or “Labelling”) and not precisely to the applicable source of information.

TÜV Rheinland has prepared this document in order to help facilitate and streamline the Technical Documentation submission and assessment process which in the end should allow the Notified Body TÜV Rheinland LGA Products GmbH (TRLP) to issue related certificate(s) under the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) and thus ensure a more efficient approach that safe and effective medical devices reach patients as quickly as possible.

For the successful processing of IVDR applications, one of the critical factors in the process is the quality and structure of Technical Documentations submitted for assessment. TÜV Rheinland encourages and highly recommends to follow this guidance when creating and submitting Technical Documentation(s).

Please note: This guidance document does not add or change any requirements defined in the IVDR, but outlines exemplarily the information and documentation expected to be within the Technical Documentation. TÜV Rheinland may request further documents and information beyond this list in line with the requirements of the IVDR in the course of the Technical Documentation assessment.

2 Submission Process

To begin...

1. Notify your contact person at TÜV Rheinland at least 90 days in advance that you will have (a) Technical Documenta- tion(s) ready for submission.
2. You will receive a quotation for the TD assessment(s) if not yet covered by an existing order.
3. Ensure you have the following ready before moving to the next step:
 - The Product List and Application [PL&A] (IVDR Annex IX/ Annex XI, part A (“QMS part”)) and where applicable, an additional application for IVDR Annex IX, Chapter II, Section 4 and 5.
 - A cover letter accompanying the Technical Documenta- tion submission containing the following information:
 - Certificate # reference(s) (if known)
 - Type of assessment (new product, design change, shelf life extension, sampled TD, etc.)
 - Product name(s) and EMDN term
 - An explanation of what has been submitted and how it demonstrates compliance and
 - For changes to existing certification:
 - What is affected (design, packaging, material change, etc.)
 - What is not affected (along with an appropriate justification)
 - The TÜV Rheinland (Significant) Change Notification (if applicable): [TÜV Rheinland | TÜV Rheinland \(TÜV.com\)](#)
 - Ensure compliance of your Technical Documentation with the IVDR, by
 - Following a clear and comprehensive structure, such as the one displayed in the Annex A checklist
 - Completing the checklist in Annex A and thus ensuring that all required documents are included and referen- ces are valid (pre-check by the manufacturer)
 - Verifying that only approved and controlled documents as per your QMS – no drafts except for the Declaration of Conformity or the SSP – containing objective evi- dence to demonstrate compliance to the IVDR (Annex I (GSPR), Annex II (TD) and Annex III (TD on PMS)) are included in the Technical Documentation
4. Submit the approved and signed purchase order and the application package (as per IVDR Annex IX, chapter II for initial submissions).
5. Submit the Technical Documentation together with the completed Annex A checklist. A thoroughly filled check- list will help TÜV Rheinland to perform the completeness check as well as the initial assessment of the TD in the most efficient way.

In addition please provide a picture of the device and, when- ever practical, a product sample. A sample is obligatory at least for specific types of devices (self-testing and near- patient testing) referred to in point (b) of Annex IX Sections 5.1 in its final packaging (to ensure symbols, description is legible).
6. The TD assessment process will start after receipt of a signed purchase order accompanied by all required applica- tion documentation.

TÜV Rheinland LGA Products GmbH (TRLP) will perform a completeness check of the Technical Documentation, in order to verify that all required TD deliverables according to Annex A have been submitted by the manufacturer.

Please note that if, during this completeness check, TRLP notices that documentation is missing, the manufacturer will be notified that the project is on hold until the complete documentation is resubmitted.

Only Technical Documentations that pass TRLP’s complete- ness check will then move to the next phase and the initial assessment of the TD can be started.

3 Preparing Technical Documentations

IVDR is a new legislation, and for initial certification a complete submission containing all relevant parts of the Technical Documentation is required.

For specific products (class D, self-testing, near-patient testing and companion diagnostic), the IVDR requires a TD assessment before initial certification. For other types of devices within class B and C, a successful assessment of one or multiple TDs per device group (term used synonymously for generic device groups (class C) and product categories (class B)) is required before certification. Additional assessments of other devices from the same group will follow based on a sampling approach over the period of the certificate validity. The Technical Documentations to be assessed for initial certification will be determined by TRLP based on the application documents provided, in line with the requirements and guidelines of the IVDR.

Furthermore it is crucial that only those products are listed on the application form, for which the manufacturer established Technical Documentations in full compliance with the IVDR. Otherwise it causes delays in the assessment and certification activities.

The Technical Documentation needs to be accompanied by a (draft) Declaration of Conformity. For products already in the market under an IVDR certificate, the copy of a recently signed Declaration of Conformity is required. For new products, a draft of the Declaration of Conformity for the product needs to be part of the application.

The Technical Documentation has to contain consistent information throughout all sections, appendices, and attachments.

3.1 Language

In the pre-application phase (i.e. before TÜV Rheinland issues a quotation for the Technical Documentation assessment), we will ask you to provide information regarding the language of the Technical Documentation. It must be an official language of the European Union. We will confirm with you at that stage whether it is feasible for us to perform the assessment in the language in which you would like to submit your Technical Documentation. We strongly recommend that you present the Technical Documentation in English language. Technical Documentation submissions in other languages of the European Union require a prior approval of TÜV Rheinland.

Original test reports submitted as part of the Technical Documentation need to be translated accordingly. Documents not submitted in the required language are considered not to be part of the submission and will be excluded from the Technical Documentation and subsequently from any assessment activities.

3.2 Electronic File Format

Annex II of the IVDR states “The Technical Documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.” Thus,

- Documents shall be provided as paginated, fully searchable, OCR (Optical Character Recognition) applied and bookmarked PDF files. Main sections as indicated in IVDR Annex II “Technical Documentation” should be bookmarked, as well as any supporting attachments referenced to within the main body (i.e. executive summaries) of the Technical Documentation.
- Clear folder organization and easy navigation will make it easier to find documents and may therefore reduce overall time required for the assessment.
- An index or detailed table of content has to be part of the Technical Documentation.
- File names should be short and self-explanatory, reflecting the information included within the documents. File names should be appropriately cross-referenced in Annex A.
- For each main section specified in the IVDR Annex II, one PDF file should be submitted containing an executive summary including the references to the accompanying documents, which contain the documented evidence (e.g. reports).
- Approvals are required for any submitted document in the TD (signed and dated files!). No draft versions (except for the Declaration of Conformity and the SSP) shall be part of the TD submission.

Please note that if the submitted Technical Documentation does not meet the electronic format and language requirements as specified in the IVDR, the TD will be not accepted for further assessment, which will cause a delay of the process. The application will be on hold until the TD has been submitted per this guidance and has passed the completeness check. Incomplete TD submissions from manufacturers are one of the most common reasons for questions being raised by Notified Body product specialists and ultimately can lead to delays in the assessment of TDs and the certification process.

3.3 Pre-check of the Technical Documentation by the Manufacturer

Therefore please check thoroughly the content and references in your Technical Documentation using the Annex A checklist, which is available as a separate [document on our webpage](#) as well as upon request from your TÜV Rheinland local contact.

Annex A contains examples of documentation expected in the different sections of the technical documentation. However, please refer to IVDR Annex II and III for the respective requirements to be addressed.

3.4 Electronic Submission Route

TÜV Rheinland can provide access to secure data transfer tools (e.g. TÜVbox) for the submission of your Technical Documentation.

We recommend that you prepare ZIP files for the document upload (or you may split your set of documents in more than one file) while keeping your binder and file structure within the ZIP file(s).

Your TÜV Rheinland office serving you will provide further details on the electronic file submission process.

4 Technical Documentation Assessment process

After the date of submission is agreed upon, the manufacturer needs to provide the submission according to section 3.4 Electronic Submission route to TÜV Rheinland on this agreed date. The first step of the TD assessment process by TÜV Rheinland is the completeness check based on the prefilled Annex A of the manufacturer. This completeness check of the Technical Documentation will be performed within 15 days after the agreed submission date.

All missing documents identified during the completeness check need to be provided by the manufacturer before the submission will progress to the next phase, the initial TD assessment.

However, failure to provide a complete TD on the agreed submission date and/or after the completeness check will lead either to a refusal or rescheduling of the TD assessment for the concerned device(s).

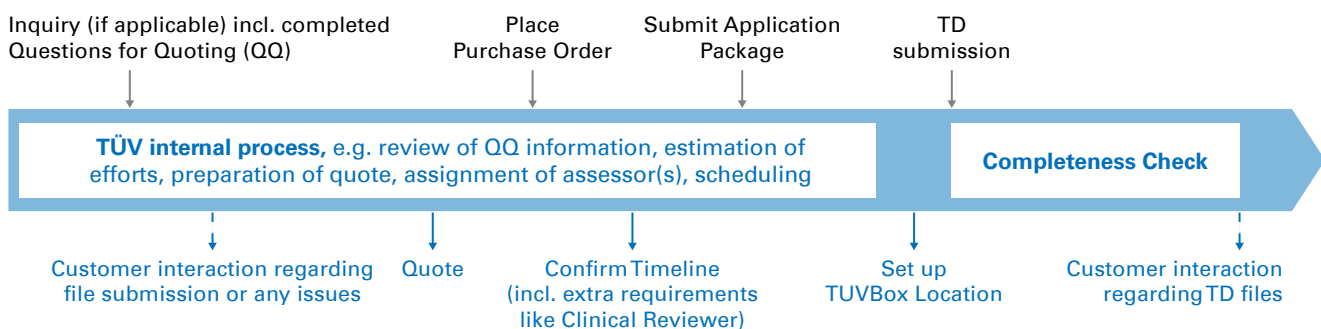


Figure 1: Typically work flow is starting at least 90 days prior to the TD review process. The arrows indicate the deliverables of the client (grey color) and the actions/deliverables of TÜV Rheinland (blue color). TÜV Rheinland confirms the TD submission date after receiving a purchase order and the IVDR application package. After receipt of the Technical Documentation, including the TD Checklist (as shown in Annex A), a Completeness Check is performed by TÜV Rheinland experts to confirm the package is eligible to proceed.

To reflect the changes made to the Technical Documentation during the Completeness Check, a redlined document of the “Annex A: Checklist for IVDR Technical Documentation Submissions” should be submitted together with the revised Technical Documentation.

Please note that during the assessment process questions from the product specialists may arise which need to be addressed by additional information to be provided by the manufacturer. In order to maintain an efficient project management, we would like to ask for your understanding that overall project timelines have to be defined and kept. **Therefore, if required documents/evidence are still missing after the 3rd attempt of the manufacturer to address the open topics, TÜV Rheinland reserves the right to cancel the project and/or decide on further measures.**

The Completeness Check of the Technical Documentation does NOT count as one of the maximum four TD assessment cycles performed by TÜV Rheinland.

Responses to TÜV Rheinland’s questions should be provided within 20 business days after receipt of the questions documented in the “Technical Documentation Assessment IVDR – Questions and Answers List”. In cases where TÜV Rheinland requires further or more detailed documented evidence of compliance to the IVDR, the Technical Documentation must be updated accordingly. To support the assessment workflow, the revised Technical Documentation must be accompanied by a revision history indicating any change in comparison to the initial submission.

The Technical Documentation shall only include **current and applicable documentation** related to the devices under assessment. New or revised documents have to be highlighted as such. Also documents, which were declared obsolete have to be indicated in the revised Annex A checklist. Obsolete or outdated documentation **shall not** be part of the submission for Technical Documentation assessment.

All answers provided by the manufacturer shall include a reference to the document number, document name, section and page number that was changed. The respective document is expected to be part of the revised Technical Documentation.

Note: If it is not obvious which parts/documents were revised or updated, the re-assessment of the complete Technical Documentation will be required, which will add assessment times and therefore additional costs.

After all questions from the product specialists have been satisfactorily addressed and the revised version of the Technical Documentation is submitted, the internal documentation needs to be prepared and the complete package delivered to the certification department for the final decision.

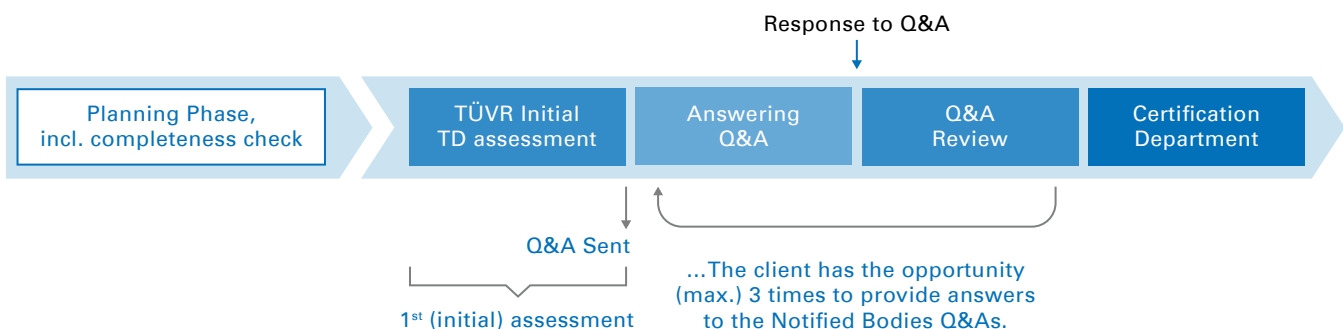


Figure 2: Scheme of the process flow following the planning phase (figure 1). After the initial TD assessment by TÜV Rheinland there will be a Q&A round, where questions from the initial assessment need to be answered by the client and time is allocated to assess the respective update of the technical documentation. Depending on the quality of the documentation and responses, a second, third or fourth (last) Notified Body assessment may be needed, leading to an extension of the assessment timeline. The TD assessment process will be finalized by the decision of the certification department.

5 Significant Change Notifications

For devices already assessed and covered by a certificate, it is crucial to describe the reason for the change(s) including its intended effect(s).

The TÜV Rheinland Significant Change Notification (SCN) forms for Product Assessment or QMS Assessment shall be used (e.g. for new products, design changes, shelf life extensions, manufacturing changes etc., depending on the risk class of the products and their conformity assessment).

For submissions in the context of scope extensions or significant changes, as far as is practical, submissions should be stand-alone and not refer to previous submissions for evidence of compliance. A consolidated revised Technical Documentation is expected, highlighting the changes in

the “Annex A: Checklist for IVDR Technical Documentation Submissions” and indicating new or revised, obsolete or replaced documents as opposed to the previous Technical Documentation revision which was already assessed. Any changes or removals of critical suppliers/subcontractors require a revised Product List and Application, along with a Significant Change Notification, if applicable.

If you remove a critical supplier/subcontractor, please also provide justification for their removal.

Note: Before another SCN for a specific Technical Documentation is submitted, the previous SCN assessment needs to be successfully assessed and closed by the certification department.

Annex A: Checklist for IVDR Technical Documentation Submissions

This checklist is a separate document, which can be found in the IVDR section on our [website](#) as well as upon request from your TÜV Rheinland local contact.

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