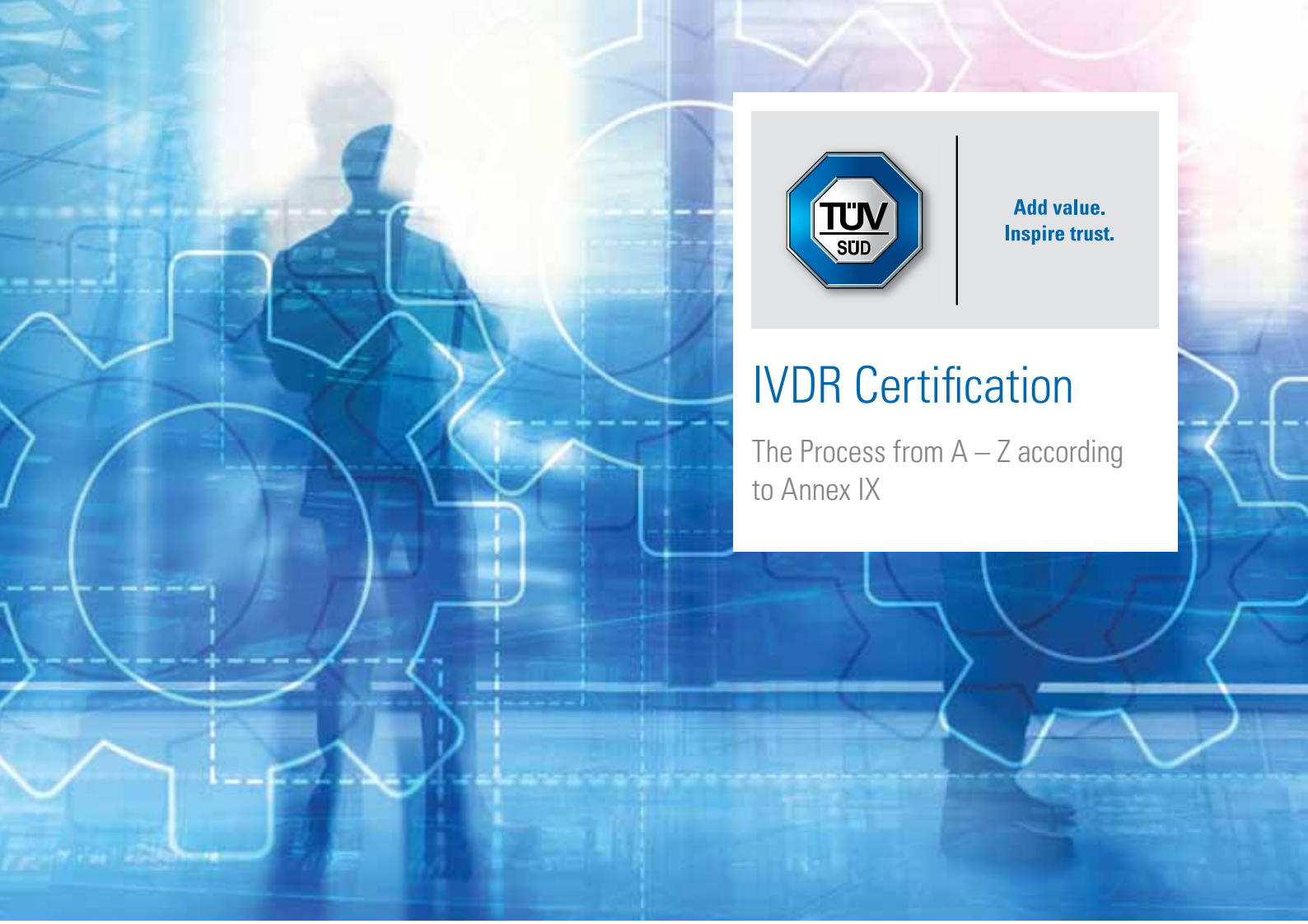

Add value.
Inspire trust.

IVDR Certification

The Process from A – Z according to Annex IX

Regulation (EU) 2017/746 of the European Parliament and of the Council (IVDR) requires all manufacturers of In Vitro Diagnostic Devices to comply with all applicable requirements of the regulation and follow one of the possible conformity assessment procedures.

Except non-sterile class A all devices need Notified Body involvement. If Annex X and / or Annex XI is / are chosen, this document is not applicable, please contact your TÜV SÜD Product Service GmbH Client Handler, to discuss the next steps.

This document describes the conformity assessment process as implemented by TÜV SÜD Product Service GmbH following Annex IX of the Regulation. Following steps must be adhered to and will be described on the following pages.

Request for Conformity Assessment	Non-binding Quotation	Formal Application	Application Review	QMS Assessment
IVDR Certification	Certification Decison	Final Review	Technical Documentation Assessment	

TÜV SÜD Product Service GmbH

I. Request for Conformity Assessment

The first step of the process is a request for Conformity Assessment by you as a legal manufacturer. Please complete the Pre-Application Questionnaire, even if you are already a customer of TÜV SÜD Product Service GmbH. The questionnaire allows us to get an overview over your company, including contacts, sites, products, suppliers and subcontractors and other relevant data, and serves as an input to our calculations and planning. The questionnaire references several Appendices, which must be completed; the same Appendices can be used for the formal application in a later process step.

If you have any questions on how to complete the questionnaire, please do not hesitate to contact your TÜV SÜD Client Handler. If there are mistakes or gaps in this first step, this might have serious impacts and delays on the remainder of the certification process.

II. Non-binding Quotation

After the questionnaire is received by TÜV SÜD Product Service GmbH, an initial pre-application check will be performed, that includes a credibility check, an Eudamed inquiry, and a general feasibility determination. Your Client Handler will contact you shortly after you sent the completed Pre-Application Questionnaire.

In many cases there will be issues to discuss or several options to consider, and TÜV SÜD will help with our expertise to navigate through those.
When all is in order, a non-binding quotation will be prepared and sent to you.

III. Formal Application

After you sent us the accepted and signed non-binding quotation, we will need the formal application documents which serve as the legal order to perform a conformity assessment according to the IVDR and contract between TÜV SÜD Product Se rvice GmbH and you as a legal manufacturer of IVD devices.

The application consists of a main application document, which must be signed, and several Appendices; the same Appendices as already completed during the request for conformity assessment (step I) can be used.
Again, if you have any questions on how to complete the application, please do not hesitate to contact your TÜV SÜD Client Handler.

IV. Application Review

After we received the formal application, we will perform an Application Management review as required by Annex VII, Section 4.3 of the Regulation.

The purpose of this review is to assess the completeness of the applications with respect to the requirements of the relevant conformity assessment, the verification of the qualification of products covered by the application as devices and their respective classifications, whether the conformity assessment procedure chosen is applicable to the device(s), the ability of TÜV SÜD Product Service GmbH to assess the application based on our designation and the availability of sufficient and appropriate resources.

The designated Project Handler – usually the Client Handler - will perform this assessment and document the outcome. The compiled application review file is then sent to our Certification Body, which is a separate department within TÜV SÜD Product Service GmbH, for assessment. A decision is taken whether the application is accepted or not. In case of negative decisions, the Project Handler will contact you, and try to resolve any issues, e.g. ambiguities with regards to intended purposes, product classifications or code assignments. If issues cannot be resolved, the process stops here, otherwise the application review file is revised and sent to the Certification Body again. After a positive decision by the Certification Body, an order confirmation is sent to you, and the project formally starts.

V. Assessment Activities

Now that the formal Application Review was performed and accepted, your personal Client Handler will plan the Technical Documentation and QMS Assessment activities, authorised Product Reviewers and Auditors will participate. You will be involved right from the beginning, so we can assure timely, effective and smooth assessments.

a. Quality Management System Assessment
When Annex IX is chosen as a conformity assessment procedure, assessment of your Quality Management System is performed by us as your Notified Body, as required by Annex IX, Chapter I; i.e., designated Auditors within TÜV SÜD Product Service GmbH will assess the conformity of your Quality Management System to the Regulation.

There will be a Stage 1 audit, where we assess if the QMS generally complies with the regulation and is complete.

If the Stage 1 audit is successful, i.e. all respective requirements are fulfilled or any nonconformities found during the audit can be closed, a Stage 2 audit will be conducted. Here the effective implementation of the QMS will be assessed. Any major nonconformities found during the Stage 2 audit must be closed, before the process can continue to the next step.

b. Technical Documentation Assessment
When Annex IX is chosen as a conformity assessment procedure, assessment of Technical Documentation is performed by us as your Notified Body, as required by Annex IX, Chapter II; i.e., designated Product Reviewers within TÜV SÜD Product Service GmbH will assess the conformity of device Technical Documentations to the Regulation.

Depending on the risk class(es) of your device(s), assessment of the Technical Documentation(s) is performed on the basis of representative samples - also called "sampling" (Class B and Class C)
For Class D, Self-Testing, Near-Patient Testing and Companion Diagnostics devices, each Technical Documentation will be assessed, there is no sampling; a separate application is needed for each of these devices.

There are separate TÜV SÜD Product GmbH info materials for Sampling of Class B and C products, and for Technical Documentation Submission Requirements, please ask your TÜV SÜD Client Handler.

After all assessment activities were performed, reports are created by the Auditors / Product Reviewer(s), that state the compliance status of the QMS / Technical Documentation(s) with the Regulation.

In case the assessment activities uncover nonconformities, i.e. any non-compliances to the respective requirements, nonconformity reports will be issued by the Lead Auditor / Product Specialist(s). These nonconformities must be closed before an assessment file can be compiled.

The compiled assessment file then is submitted to the Certification Body.

VI. Final Review

Prior to making a final decision on issuance of a certificate, a final review must be performed by technical certifier(s). Technical certifier(s) are always different from the personnel who have conducted the assessments. The technical certifier verifies that the report or reports and supporting documentation needed for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application, and whether there are any unresolved non-conformities preventing issuance of a certificate.
If there are any issues, the Project Handler will try to resolve them with your help, if needed. Although rare, even at that late stage there might be issues that cannot be resolved or might need a revised application or assessment.

VII. Certification Decision

After final review the technical certifier(s) decide based on the assessment documentation and additional information available whether the requirements of the IVDR are fulfilled. Decisions are taken whether the certificate(s) applied for are issued.
The decision made can imply the need for additional surveillance activities related to certificates, like specific milestones for further review by the notified body of the up to date performance evaluation,
The decision made can include specific conditions or provisions for the certification.

VIII. IVDR Certificate

In case of a positive decision the certificate(s) are issued. In case of an assessment of the quality management system you will receive a EU quality management system certificate (IVDR). In case of an assessment of the technical documentation (class D, class B/C self/near patient testing, class C companion diagnostics) you will receive a EU technical documentation assessment certificate (IVDR).
The certificates serve as evidence that TÜV SÜD Product Service GmbH conducted a conformity assessment according to Annex IX of the IVDR and that all applicable requirements are fulfilled.

Please be aware that for placing on the market of class D, class B/C self/near patient testing, class C

companion diagnostics you as a manufacturer must hold both certificates, the EU quality management system certificate (IVDR) as well as EU technical documentation assessment certificate (IVDR). For more information on this topic, please see also the TÜV SÜD document on conformity assessment procedures for the different device types and classes.

IX. Surveillance Activities / PSUR / Changes

In step VIII above you finally received your IVDR certificates which is a great milestone! However, here the process does not end, it just has started really. There will be annual surveillance audits (if applicable including assessment of Technical Documentations on a representative basis), unannounced audits, Periodic Safety Update Reports, additional surveillance activities as described in VII above, any significant changes to your QMS and products may need assessment etc.

X. Frequently Asked Questions

Q: I am already certified according to the IVDD, can I have a simple upgrade audit to get an IVDR certificate?
A: No, there is no 'grandfathering', neither for products, nor for QM systems. The process is the same as for completely new clients / products.

Q: We have products already certified under the IVDD, can we "upgrade" them to IVDR?
A: No, there is no "grandfathering", all product certifications will be handled as initial certifications. You can use already existing data and documentation provided these include the information required under the IVDR and evidence for compliance. There is a separate Customer Information Material for Legacy Products, please ask your personal Client Handler.

Q: I have a planned audit (e.g. EN ISO 13485:2016), can I combine the IVDR audit with the already scheduled one?
A: Yes, the audits can be combined, and will result in a reduced audit time, compared as to two separate audits.

Q: Can I hold an IVDD and IVDR product certificate at the same time?
A: Yes, until May 26th 2024 this is possible. For products the Declaration of Conformity (and other labeling if applicable) then should clearly indicate if the product

was placed on the market under IVDD or IVDR requirements.

Q: There are so many documents to complete, can you consult me what to complete and how?
A: No, consultant activities must not be performed by any Notified Body. We will provide you with forms for application and information how to use them; however, we will not provide details on how you meet or implement any regulatory requirements.

Q: How long does it take to get the IVDR certificate?
A: There is no general answer to that question unfortunately, and largely depends on the certificate scope(s), company size, and availability of resources. However, the sooner we can start planning, the faster we can start the process. Also, we expect to have more inquiries than we can handle immediately, so there might be a queue.

Q: I am at another Certification / Notified Body at the moment with an ISO 13485 / IVDD. Can I switch or transfer?
A: The IVDR certification will be an initial certification, so there is no possibility to transfer any existing ISO or IVDD certification to an IVDR certificate. However, if you have a valid IVDD and/or ISO 13485 certification, you can of course choose to switch to TÜV.

Q: With regards to implementation of IVDR requirements: Should CLSI, GHTF or other guidelines be used, when no Harmonised Standards for IVDR exist?
A: International guidelines can be a good basis, but they do not always meet the requirements of the IVDR. Reference should always be the IVDR and MDCG guidance documents, if available.

Q: I have several devices classified as Class B, C and D. How will sampling and Technical Documentation assessment look like?
A: There is a separate Customer Information Material for sampling of Technical Documentation, please ask your personal Client Handler.

Q: I am preparing Technical Documentations for devices, what should be the structure and how can I submit them?
A: There is a separate Customer Information Material for Technical Documentation Submission Requirements, please ask your personal Client Handler.
Q: How can we best show where and how we implemented IVDR requirements for our QMS that are different to IVDD and/or ISO 13485:2016?
A: There is a separate Customer Information Material for QMS System Requirements, where you can enter where and how you implemented those requirements, please ask your personal Client Handler.

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
+49 89 5791-0 medicaldevice@tuvsud.com www.tuvsud.com/medicaldevice