A GUIDE TO ACHIEVE IVDR COMPLIANCE

EU Declaration of Conformity

QRcompliance
QUALITY AND REGULATORY SERVICES

Contents

Introduction

The regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices, lays down the rules concerning the placing on the market, making available on the market or putting into service of in vitro diagnostic medical devices for human use and accessories for such IVDs in the European Union.

This guide explains the requirements of the IVDR regarding the EU Declaration of Conformity.

I hope you find this guide informative and enjoyable to read.

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Explanation of Terminology

This chapter presents a comprehensive glossary aimed at providing a clear understanding of the specialized terminology used throughout this guide. The included terms are carefully chosen to address concepts that may require additional explanation beyond their initial presentation. By consulting this glossary, professional users can navigate the guide with enhanced clarity and grasp the intended meanings of the terms used.

An **in vitro diagnostic medical device** (IVD) refers to any medical device intended by the legal manufacturer to be used in a laboratory setting for examining specimens derived from the human body, this includes blood and tissue donations. IVDs can be reagents, calibrators, controls, kits, instruments, software, or systems, either used alone or in combination.
The intended purpose of an IVD is to provide information about physiological or pathological processes, congenital impairments, predisposition to medical conditions, safety and compatibility with potential recipients, treatment response or reactions, as well as defining or monitoring therapeutic measures.
It is important to note that specimen receptacles are also considered IVDs.

An **accessory** for an in vitro diagnostic medical device refers to an article that, although not an IVD itself, is designed by the legal manufacturer to be used with one or more specific IVD(s). Its purpose is to enable the IVD(s) to be used effectively and in accordance with their intended purposes, or to directly enhance the medical functionality of the IVD(s) for their intended purposes. An accessory complement and supports the proper functioning and usage of the associated IVD(s), enhancing their capabilities or facilitating their intended purpose.

The **intended purpose** of an IVD refers to its designated use as defined by the legal manufacturer through information provided on the label, instructions for use, promotional materials, sales statements, or as indicated by the manufacturer during performance evaluation. It outlines the specific applications or functions for which the IVD is designed and intended to be used. Understanding the intended purpose is crucial for ensuring appropriate and accurate utilization of the IVD.

A **legal manufacturer**, in the context of IVDs, refers to a natural person or a legal entity that is responsible for the production, assembly, or refurbishment of an IVD. They may also be involved in the design, development, or manufacturing process of the device. The legal manufacturer assumes the responsibility for ensuring compliance with applicable regulations, conducting appropriate quality control measures, and placing the IVD on the market under their own name or trademark. They have legal obligations and liabilities associated with the safety, performance, and regulatory compliance of the medical device.

An **authorized representative**, in the context of IVDs, is a natural person or legal entity appointed by the legal manufacturer, who acts on behalf of the legal manufacturer regarding certain regulatory obligations. The authorized representative is typically based within the European Union (EU) and serves as the legal manufacturer's representative within these

regions. Their role includes ensuring that the legal manufacturer's obligations, such as conformity assessment procedures and post-market surveillance activities, are fulfilled in compliance with the applicable regulations. The authorized representative may also manage communication with regulatory authorities on behalf of the legal manufacturer.

Placing on the market refers to the initial act of making an IVD available on the European Union (EU) market, excluding IVDs intended for performance studies. It signifies the first instance of introducing the IVD to the market, making it accessible for distribution, sale, or use within the EU.

Making available on the market refers to the act of supplying an IVD for distribution, consumption, or use within the EU market as part of a commercial activity. This includes all instances where the IVD is provided, whether for a fee or free of charge, excluding instances where it is specifically intended for performance studies.

Putting into service refers to the moment when an IVD is made available and ready for use by the end-user for its intended purpose. It signifies the stage when the IVD device is provided to the user and can be utilized for diagnostic or testing purposes.

An **IVD for performance study** refers to an IVD that is specifically intended and designed for the purpose of evaluating its performance characteristics. These studies are conducted to assess the analytical and clinical performance of the IVD device. IVDs for performance study are typically used in controlled research or validation settings to gather data and evaluate the device's capabilities before it is made available for routine clinical use or placed on the market.

EU Declaration of Conformity

The EU Declaration of Conformity (DoC) is a legally binding document that plays a crucial role in the conformity assessment procedure for IVDs. It must be prepared and signed by the legal manufacturer, signifying their commitment to fulfilling the requirements outlined in the IVDR (In Vitro Diagnostic Regulation, Regulation (EU) 2017/746) and other relevant EU legislation. The DoC serves as a testament to the compliance of the IVD device with applicable regulations.

Contents of the DoC

The DoC should include essential information to ensure transparency and traceability.

- The name, registered trade name or trademark, and Single Registration Number (SRN) of the legal manufacturer.
- If applicable, it should also mention the authorized representative's details.
- A statement within the DoC must clarify that it is issued under the sole responsibility of the legal manufacturer.
- The Basic UDI-DI (Unique Device Identifier - Device Identifier) of the IVD, along with its product and trade name. Also, a clear product code, catalogue number, or any unambiguous reference allowing identification and traceability of the IVD covered by the DoC should be included. The Basic UDI-DI may supplement this information.
- The intended purpose and risk class of the IVD device should be stated explicitly.
- The DoC must declare conformity with the IVDR (EU Regulation 2017/746) and any other relevant EU legislation that necessitates the issuance of an EU declaration of conformity.
- If Common Specifications (CS) have been employed, references to these should be provided. Similarly, references to any relevant (harmonized) standards should be mentioned, specifying the version and/or date of these standards.
- If a notified body has been involved, the name and identification number of the notified body, along with a description of the performed conformity assessment procedure and relevant certificate(s) issued, should be included.
- The DoC must clearly state the place and date of its issuance, the name and function of the person who signed it, and an indication of, and on behalf of whom, the person signed, along with their signature. The person signing the DoC could be the Managing Director of the company or another representative of the company to whom this responsibility has been delegated.

Translation and Retention

The DoC must be translated into the official EU language(s) as required by the member state(s) where the IVD is made available. It is the responsibility of the legal manufacturer or the authorized representative, established within the EU, to retain the DoC for a minimum period of ten (10) years from the date of placing the IVD on the EU market. This ensures the availability of the DoC for reference and regulatory compliance purposes.

Continuous Updates

The legal manufacturer has an ongoing obligation to keep the DoC updated. If any of the elements within the DoC change, a revised version must be prepared for IVDs placed on the EU market after that change. Such changes may include alterations in legislation, updates to harmonized standards, or modifications to the contact details of the legal manufacturer or authorized representative.

However, the DoC remains valid for the IVD device as long as no significant product changes occur. Examples of significant changes include extensions or major modifications in the intended purpose, alterations to the operating principle, or changes in essential ingredients or materials necessary for the device's functioning (e.g., primers, antibodies, etc.).

Availability to Competent Authority

Upon request, the legal manufacturer must provide the DoC to the competent authority for review and verification purposes.

Conclusion

The EU Declaration of Conformity (DoC) is a crucial document that attests to the compliance of an IVD device with the IVDR and other applicable EU legislation. It demonstrates the legal manufacturer's commitment to meeting the requirements and regulations, ensuring transparency, traceability, and the safety of the IVD devices placed on the EU market. By diligently adhering to the guidelines outlined in the DoC, manufacturers contribute to maintaining the quality and reliability of IVD devices for the benefit of healthcare professionals and patients alike.

Process Flow to Ensure Regulatory Compliance

Creating an EU Declaration of Conformity for the In Vitro Diagnostic Medical Devices Regulation (IVDR) involves several steps to ensure compliance with the regulatory requirements. Below is a representation of the process flow for the creation of an EU Declaration of Conformity conforming to the IVDR.

Regulatory Plan	Inventory relevant directives, regulations, Common Specifications, and (harmonized) standards.
Classification	Identify the intended purpose of the specific IVD and classify it based on the IVDR classification rules.
Technical Documentation	Gather and compile all technical documentation related to the IVD, ensuring comprehensive coverage of all the aspects outlined in Annexes II and III of the IVDR.
Conformity Assessment Route	In accordance with the IVD classification, ascertain the suitable conformity assessment route and involve a Notified Body if necessary.
Conformity Assessment	Conduct the conformity assessment process according per the selected route and prepare and compile all necessary documentation related to the assessment.
Quality Management System	Establish a quality management system (QMS) and ensure that the QMS complies with the relevant harmonized standards.
EU Declaration of Conformity	Draft the EU Declaration of Conformity document.
Technical File	Create a comprehensive technical file about the IVD, include data on design, manufacturing, performance, and clinical evaluation.
Labels and Instructions for Use	Develop labels and an IFU in compliance with the IVDR requirements, ensuring that the labelling includes the required symbols, warnings, and other essential information.
PMS and Vigilance	Implement Post-Market Surveillance (PMS) and vigilance procedures.
Authorized Representative	If the Legal Manufacturer is based outside the EU, appoint an Authorized Representative within the EU.
Issue EU Declaration of Conformity	Sign and date the EU Declaration of Conformity and make it available to the Competent Authorities upon request.
Affix CE Marking	Affix the CE marking to the device or its packaging, ensuring the CE marking is visible, legible, and indelible.
Market the IVD	After successful conformity assessment and CE marking, the IVD can be marketed in the EU, with continuous compliance monitoring through regular reviews and updates to technical documentation and conformity assessment based on regulatory changes.

It is important to note that the IVDR is a complex regulation, and Legal Manufacturer's should thoroughly review the regulation itself and seek expert advice to ensure full compliance throughout the process. The above process flow provides a general overview of the main steps involved in creating an EU Declaration of Conformity for an in vitro diagnostic medical device under the IVDR.