GeneProof®

FAQ

IVDR FAQ - What does it mean for laboratories?

Q: How will the new IVDR rules affect my laboratory?

A: The current IVDR rules require laboratories to use in vitro diagnostic devices (IVDs) that comply with the new regulation. If your lab is already using GeneProof products, it is in compliance as we have met all IVDR requirements for our class “A” products.

Q: How is GeneProof prepared for IVDR?

A: GeneProof’s class “A” products and Quality Management System are fully compliant with IVDR . Our class “A“ products (Nucleic Acid Extractions and all Instruments) are CE certified to IVDR requirements and we are on track to achieve compliance for all class “B”, “C”, and “D” products on or before the mandatory deadline.

Q: Can I use RUO products in my lab?

A: IVDR tightens restrictions on the use of RUO products but does not forbid their use when used only for non-clinical purposes. However, for any in vitro diagnostic uses, RUO products are prohibited and only products that comply with IVDR may be used.

Q: What are the rules under IVDR for extraction kits used for PCR diagnostics?

A: Extraction kits are classified as class “A” under IVDR. As of 27 May 2022, all IVD extraction kits (including instruments and associatedaccessories) must have the new EU Declaration of Conformity meeting the requirements of the IVDR legislation.

Laboratories using IVD products that do not meet this requirement are acting in breach of IVDR and may be subject to sanctions under the relevant national legislation.

All GeneProof class “A” products have the proper Declaration of Conformity and **meet all IVDR requirements** for this class of in vitro diagnostic medical devices.

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Q: Why is CE IVD product certification so important?

A: CE IVD certification means that the product complies with the relevant applicable EU legislation, has the declared characteristics, and the manufacturer takes full responsibility for it.

In terms of patient safety, the use of RUO (Research Use Only) products in clinical laboratories is **prohibited in the European Union for any human diagnostic use.**

Q: Can I still use tests developed by my lab?

A: So far yes, but the new IVD Regulation is very strict on this issue, although the deadlines have been extended. Currently, IVDR requirements do not only apply to devices manufactured and used within a **single legal entity.** Within two years, laboratories using in-house methods must ensure that certain specified conditions have been met.

Q: What conditions will a laboratory using in-house methods have to meet under IVDR?

A: The laboratory can only use if there are no commercially available CE IVD products in the EU.

The laboratory must then have/comply with:

- General Safety and Performance Requirements (Annex I, IVDR)
- A quality management system which covers **manufacturing** of the IVD devices used
- ISO 15189 certification (Medical laboratories - Specific quality and competence requirements)
- Justification for the use of in-house IVD
- CAPA system
- Overview of experience gained from clinical use of the device
- Post-market surveillance system in place

Do you want to ask more? Do not hesitate to contact us on **marketing@geneproof.com**

For more info about IVDR visit our website **geneproof.com**

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