GeneProof®

FAQ IVDR

IVDR - What does it mean for laboratories?

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

A: Not if you use **GeneProof products**.

Q: **How is GeneProof prepared for IVDR?**

A: The GeneProof Quality Management System and GeenProof products are **fully compliant with IVDR** as amended. GeneProof's class „A" products (Nucleic Acid Extractions and all Instruments) are CE certified to IVDR requirements and the company is successfully progressing towards the planned IVDR certification of all its class „B", „C" and „D" products as planned.

Q: **Can I use RUO products in my lab?**

A: No. The use of IVD products that are not properly CE certified (*in accordance with the IVDR as amended*) **is strictly banned** in clinical laboratories in the European Union.

Q: **What are the current rules for extraction kits for PCR diagnostics?**

A: Extraction kits are classified as **Class A** under the IVDR Regulation and as such must be CE marked (IVDR) from the date of application of the Regulation (i.e. 27 May 2022). This means that all IVD extraction kits (and instruments, accessories etc.) **manufactured after 26 May 2022 must have a new EU Declaration of Conformity** meeting the requirements of the new IVDR legislation.

Laboratories using IVD products that do not meet this requirement are acting in breach of EU Regulation 2017/746 as amended (i.e. IVDR) and may be subject to sanctions under the relevant national legislation.

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

FAQ's continue on the next page

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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 unregulated RUO (Research-Use-Only) products in clinical laboratories **is prohibited in the European Union for any diagnostic** in human medicine.

Q: Can I still use tests developed by my lab (in-house methods, LDT)?

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 could only use in-house tests 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)
- Quality management system covering the **manufacture** 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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