Impact of IVD legislation renewal on the compliance of GenomEra® SARS-CoV-2 2.0 Assay kit

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Introduction to IVDR

Legislation on in vitro diagnostic (IVD) medical devices in Europe is changing on **26 May 2022** when the **IVD Regulation (IVDR 2017/746)** is implemented. New IVD devices must meet the IVDR requirements after this deadline. Devices already on the market will have longer transition periods.

The IVDR sets many new requirements and eases and centralizes monitoring of devices done by competent authorities:

- The devices will be classified to risk classes A–D
- High number of products will move under the compliance assessment activities performed by notified bodies (NB)
- European database on medical devices (EUDAMED) is created to collate information regarding devices
- UDI-system (Unique Device Identification) will be set up to enhance traceability of devices
- Manufacturers need a system for post-market surveillance and must regularly report the safety and performance of all devices

Structure of the device's technical file

The technical file of the IVD device must include the eight sections of requirements specified in the IVDR Annex II Technical documentation, Annex III Technical documentation on Post-Market surveillance and Annex VIII Performance evaluation and Post-market performance follow-up.

1. Device description and specification
2. Information to be supplied by the manufacturer
3. Design and manufacturing information
4. General safety and performance requirements
5. Benefit-risk analysis and risk management
6. Product verification and validation
7. Post-market surveillance
8. Performance evaluation, post-market performance follow-up

GenomEra SARS-CoV-2 2.0

The GenomEra® SARS-CoV-2 2.0 Assay Kit is a qualitative rapid IVD test which is used to aid in the diagnosis of SARS-CoV-2 virus from upper respiratory swab samples. The product, which is for professional use only, utilizes RT-PCR to amplify viral RNA on GenomEra CDX system (Abacus Diagnostica – part of Uniogen). The 2.0 kit is an enhanced version of a SARS-CoV-2 assay kit from the same manufacturer.

The product was launched in January 2022 in accordance with the current European legislation (IVD directive 98/79/EY9). The assay kit is an IVDR **risk class D device.**

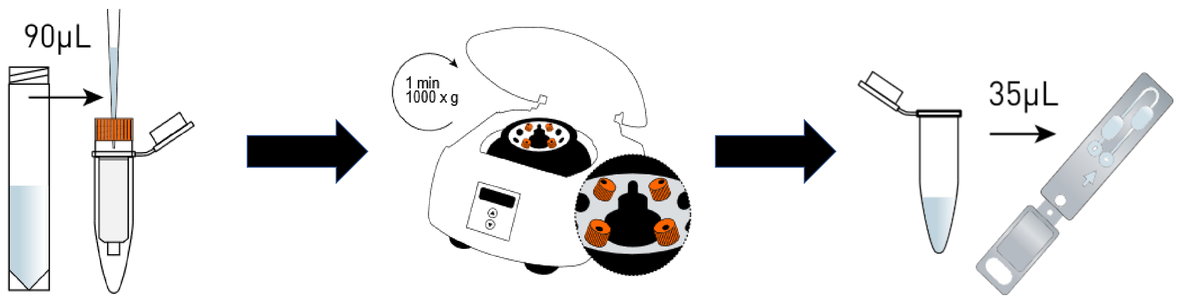

Figure 1. Sample preparation protocol with GenomEra SARS-CoV-2 2.0 Assay kit. The virus is lysed with viral transport medium and the lysed sample is transferred into GenomEra Extraction-column. The sample is centrifuged and the purified flow-through is transferred to GenomEra test chip which contains all reagents needed for RT-PCR in dry form. The samples are automatically analysed in GenomEra instrument in just 50 minutes.

Aim of the project

The aim of the Master's thesis project was to assess the compliance of the GenomEra SARS-CoV-2 2.0 Assay kit by evaluating its technical file against the requirements of IVDR.

The thesis project was a part of a bigger company project to update all manufactured IVD products to be in compliance with the IVDR.

Figure 2. Opened GenomEra SARS-CoV-2 2.0 Assay kit box

Gap analysis on the technical file

Gap analysis was used as a **tool to assess the compliance** of the GenomEra SARS-CoV-2 2.0 assay kit. In the analysis the technical documentation of the assay was evaluated against the requirements of IVDR. The result of the analysis is a **description of the current situation**, which identifies any deficiencies in the documentation. In addition to the IVDR, appropriate harmonized standards and guidance documents assisted in assessing compliance.

Risk class D device on the European market

Based on IVDR Annex VIII Rule **1**, second indent, all SARS-CoV-2 IVD products are classified in class D. The transition period for class D products already placed on the market ends on **26 May 2025.** After this, products which are not in compliance with IVDR, **can't be sold in Europe!**

Requirements on the risk category D devices on the European market:

- Conformity assessments activities by a notified body before being CE-IVD certified → Time consuming process where the NB evaluates manufacturer's Quality Managements systems and technical documentation of the device
- Each device batch documentation must be accepted by notified body before being placed on the market
- Laboratory testing of the device batches to verify their performance by EU reference laboratories
- Annual "Periodic Safety Update Report" (PSUR) to Eudamed
- "Summary of Safety and Performance" report to be publicly available
- EU Declaration of Conformity and CE-IVD-mark with the NB's identification number

Results and conclusions from Gap analysis

Design, manufacture and labeling of the GenomEra® SARS-CoV-2 2.0 Assay Kit largely meet the requirements of the IVDR. Analytical and clinical performance studies have been performed appropriately and based on guidance documents. However, the post-market surveillance activities and the required performance evaluation reports for the product are deficient.

The technical documentation of the product still requires updates of existing documents, preparation of new reports and further evaluation before it can be submitted to a notified body for assessment. The compiled gap analysis has been a great first step to recognize and fix the existing deficiencies in the technical documentation.

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