Bremen, November 2024

Dear Sir or Madam,

the IVDR is of great importance for both, you and Molzym. Therefore, we will ensure that you are informed in a timely manner about any short- or long-term changes to our products.

The In-Vitro Diagnostic Regulation (IVDR)

The IVDR (EU 2017/746), which came fully into force on May 26, 2022, increases the requirements for safety and reliability for in-vitro diagnostics. To be IVDR-compliant, additional clinical performance and risk assessments are required to ensure the safety and effectiveness of our products. These improvements benefit patients, clinicians, and laboratory experts alike.

Key changes introduced by the IVDR include a new risk-based classification system and enhanced post-market surveillance. In-vitro diagnostics are now categorized into classes A, B, C, and D, with varying regulatory requirements based on risk. Class A includes low-risk products, while Class D covers those with higher risk.

For products already approved under the IVDD (98/79/EC), extended transition periods were last set on July 9, 2024. The current transition periods are:

- Class A: There is no extended transition period (exception sterile products)
- Class B: Until December 31, 2029
- Class C: Until December 31, 2028
- Class D: Until December 31, 2027

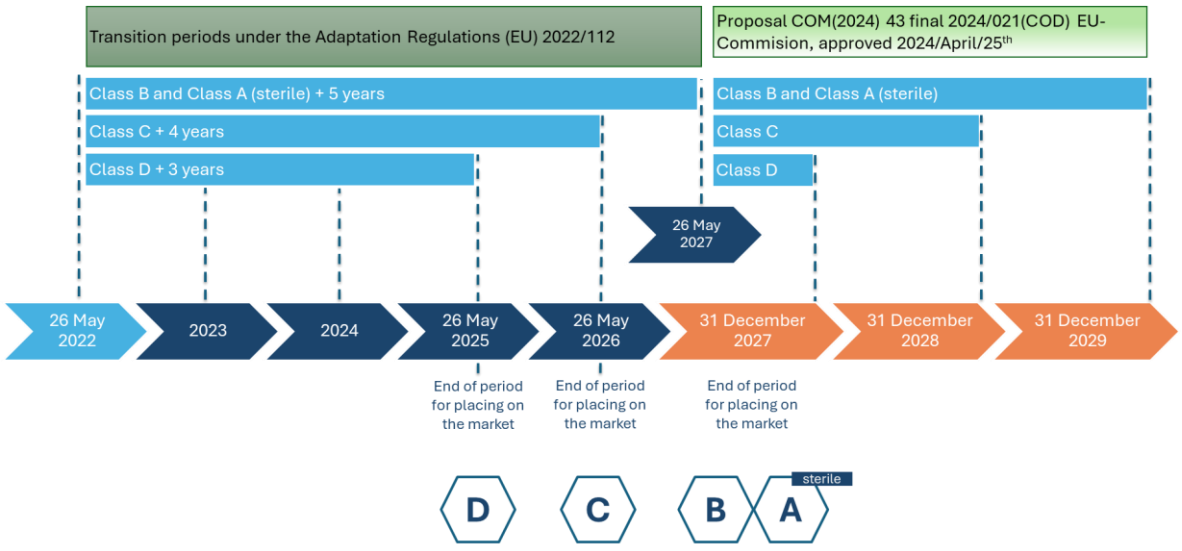

Figure 1: Transition periods for the changeover from IVDD to IVDR

Which Molzym products will be transitioned to the IVDR?

We plan to transition the two Class C tests, **SepsiTest-UMD™ CE IVD [U-010-xxx]** and **Micro-Dx™ CE IVD [U-200-xxx]**, to the IVDR by December 26, 2026 - 2 years before the EU's deadline. This will ensure continuous availability of these products.

Which steps of the workflow are covered by the IVDR?

The IVDR certification covers the workflow up to the positive/negative pathogen detection by real-time PCR. Subsequent identification through sequencing and data analysis is the responsibility of the user and is not part of the IVDR certification.

What changes will occur with IVDR products?

The sole detection method will be real-time PCR. Gel electrophoresis will no longer be included in the protocol for IVDR-compliant successor products.

Is the SelectNA™*plus* IVDR-compliant?

The **SelectNA™*plus*** instrument, required for the automated processing of the **MolYsis-SN*plus*™ IVD** and **Micro-Dx™ CE IVD** products, is already registered under (EU) 2017/746 and is thus approved for IVDR-compliant use. For other instruments mentioned in the respective instructions for use, such as real-time cyclers, Molzym defines specifications to be followed, including the use of CE-registered devices.

Which Molzym products will not be transitioned to the IVDR?

The following IVDD products will not be transitioned and will be discontinued on December 31, 2028:

- **UMD-SelectNA™ CE IVD [U-050-xxx]**
- **Add-On 10 CE IVD [U-120-xxx]**

When will Molzym launch its first IVDR-compliant product?

In 2024, Molzym will launch **MolYsis-SN*plus*™ IVD** Kit as its first Class A IVDR product. This automated test system, operated on the SelectNA™*plus* instrument, will handle human DNA depletion and the subsequent isolation of microbial DNA.

Our dedicated team is working closely with the notified body DEKRA and regulatory authorities to ensure a smooth transition. We will keep our partners and customers regularly updated on our progress and any relevant changes.

For further information, please contact our regulatory affairs team at info@molzym.com.

Thank you for your continued trust in Molzym.

Kind regards,

Dr. Michael Lustig
CEO