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Information – Transition to IVDR

As IVD medical device manufacturer, we want to highlight here the current regulatory changes we are going through, how we address them and the benefits expected for our products' users and for the IVD market overall.
We know how important it is for you to hear in good time about any short- or long-term changes concerning our products and will, of course, continue to keep you up to date.

The IVDR

In Europe, laboratories, users and manufacturers of in vitro diagnostic medical devices are affected by immense regulatory changes. The new In Vitro Diagnostics Regulation (IVDR, (EU) 2017/746) entered into force in 2017 and fully applied since 26th May 2022. It replaces the In Vitro Diagnostics Directive (IVDD, 98/79/EC).
However, extended transition periods have been set for products already authorized under the IVDD – which is the case of our already commercialized and in-use products SepsiTest™-UMD and Micro-Dx™.

The new IVDR provides more transparency and comparability in clinical performance evaluation and post-market surveillance. It is a further step towards harmonization with international regulatory conventions for in vitro diagnostic medical devices.
These improvements will benefit patients, clinicians and laboratory experts alike.

New transition periods

IVDR transition periods to place IVDD products on the market will be extended according to the IVDR risk class:

- For future class D devices, until 26 May 2025 (e.g. highly pathogenic viruses, Lassa virus, Ebola virus, HIV, HBV, HCV).
- For future class C products, until 26 May 2026 (e.g. most other pathogens, herpes/polyomaviruses, HAV, HEV, WNV, DENV, CHIKV, Plasmodium species).
- For future class B products, until 26 May 2027 (e.g. norovirus, rotavirus, non-pandemic influenza A/B virus, RSV, hMPV).
- Future Class A devices must be IVDR compliant since 26 May 2022.

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Molzym's CE IVD products

Changes introduced by the IVDR include, for example, a new risk classification system and improved post-market surveillance and transparency.
In this context, Molzym has been enhancing capacities for years and investing in the implementation of the IVDR for the already IVDD-labelled products SepsiTest™-UMD and Micro-Dx™ and the development of further innovative products. As Class C devices, such products will transit latest in May 2026 from IVDD to IVDR compliance and dedicated labelling, as illustrated hereafter.

We recognize the need of our customers for extraction products in IVDR compliant quality for Sanger and NGS-based sequencing assays. Therefore, Molzym thrives to provide our customers with products adopted to state of the art diagnostic tests. Details on products for use with NGS-based analyses will follow.

We hope this letter has brought clarity on the current regulatory changes our field is living. We remain at your disposal should you have any questions.

Best regards,

Gabriel Tirouflet
Molzym CEO