
IVDR -
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together.
TECAN.

TECAN IS IVDR READY.

You might be aware that your current supplier is discontinuing its niche products and now you are looking for alternatives?

Tecan‘s current portfolio has been reviewed to ensure compliance and a seamless transition of available products for clinical laboratories. All IBL International CE-IVDD products have been classified according to the classification rules laid out in the IVDR allowing sales during the accepted transition period. Contact us to receive the latest version of our catalog for an overview of the portfolio!

New IVDR transition period.

The IVDR has been in effect since May 2017 and was originally scheduled to come into force on May 26, 2022. However, the European Commission published additional Regulation (EU) 2024/1860, ammending the IVDR to further extend the transition timeline for the introduction of the IVDR when certain conditions are met. Products that have been CE-IVDD marked prior to May 26, 2022, can continue to be manufactured and sold for an extended period but only if no significant changes are made to the intended use or design. Despite this extended transition period, certain IVDR requirements still apply to all in vitro diagnostic devices, including those that continue to be CE IVDD labeled, since May 26, 2022. These requirements include market surveillance and post-market surveillance of the product, vigilance, registration of economic operators and registration of devices. With the latest amendment the previously applicable transition periods have been extended by further 2.5 years for class B-D devices, but are subject to additional conditions. These include posing no unacceptable risk to health or safety, manufacturers having an IVDR QMS in place by 26 May 2025, lodging formal IVDR application by applicable deadline as well as a signed agreement with the Notified Body.

Why should clinical laboratories care?
Here are the five main reasons you should know:

1. **Know when you need to act**: Although there is no immediate need to switch from „IVDD“ to „IVDR“ products, laboratories should be aware of the transition periods for the various device classes.

2. **Start on time**: Laboratories need to keep in mind that products not yet certified under the IVDR will need to be assessed by a Notified Body in the future. Notified Body assessments are lengthy and complex processes.

3. **Stay informed**: For devices not yet IVDR certified, the lab can request transition plans from manufacturers.

4. **Keep track of IVDD product changes:** IVDD products can still be manufactured and sold after May 26, 2022, however, all additional conditions must be met and no significant changes to the design or intended purpose are possible. Once the product needs to be changed, it can only be sold with an IVDR certificate. Manufacturers must allow for a longer time to market for modified or new products.

5. **Don‘t panic**: When a lab switches from IVDD to IVDR products, there are generally no additional requirements for the user. If the product is the same and only the certification has been changed, no new validation is required.

Are you ready for a new chapter?

The In Vitro Diagnostics Regulation (IVDR) is the new regulatory framework to ensure the safety and performance of in vitro diagnostic devices on the European market. The IVDR replaced former EU Directive on In vitro Diagnostic Medical Devices (IVDD 98/79/EC) and came into effect May 26, 2022.

This also means that the majority of all in vitro diagnostic medical devices previously placed on the market in compliance with the IVDD have to be recertified according to the new requirements. Manufacturers must demonstrate compliance with the new IVDR requirements.

The IVDR introduced a risk-based classification system, which requires the involvement of a Notified Body in the approval of class A sterile through D, while class A non-sterile IVDs remain self-declared and D representing products with the highest risk to patients and public health. It is expected that approximately 90% of all IVDs on the market will be evaluated by a Notified Body. In comparison, this has previously applied to less than 15% of IVDs under the IVDD.

Another feature is a new system for unambiguous product identification of IVDs, known as the Unique

Device Identification Number (UDI), which will be used in the documentation, registration and on the finished product.

The UDI is intended to facilitate the traceability of products within the supply chain and to enable a fast and efficient recall of IVDs that pose a safety risk, as well as provide visibility and transparency for the customer.

What does this mean for laboratories/customers?

First things first: You as a customer or user are not responsible for implementing the legal framework and requirements for the IVD. Any product you find on the market with a CE marking after May 2022 will comply with the legal requirements. However, this does not mean that all products whose IVDR-compliant technical documentation has not yet been finalized will disappear after May 26, 2022, but that there will be a transition period to sell products after that date and to bridge supply needs. The complex regulatory process, conditions and rules are summarized in Article 110 of the IVDR. Some IVDs with Directive certificates issued by Notified Bodies under the Directive can still be sold and placed on the market until Dec 31, 2027 when all additional conditions are met (QMS, formal application lodged, NB agreement signed). Not all manufacturers have an agreement with a Notified Body, which is a requirement for CE-IVDR devices (Class B, C, D and A sterile), and not all Notified Bodies are designated for the IVDR (lack of market access).

Regulation beats innovation!

The market will change and with it the product range. This could possibly also affect products that you as a customer buy for your daily routine in your laboratory. As a supplier of routine and niche parameters, Tecan is interested in continuing to develop innovative products particularly for rare diseases. Tecan is at the forefront of IVDR product certification. Together with our Notified Body we have already successfully obtained IVDR certification for numerous products, and many more are in the pipeline.

IVDR transition timeline.

In case the additional conditions are not met completely, former transition timelines still apply (26 May 2025 for class D + IVDD certificate, 26 May 2026 for class C, 26 May 2027 for class B and A sterile.)

Autoimmunity

- Acetylcholine Receptor Autoantibodies (ARAb) RRA (30221148; IVDR version of RE21021), 100 Tests
- Acetylcholine Receptor Autoantibodies (ARAb) RRA (30221149; IVDR version of RE21023), 30 Tests
- MuSK-Ab ELISA (RE51021)
- dsDNA-Ab RIA (RE19011)

Catecholamines / Neurotransmitters

- Histamine ELISA (RE59221)
- TriCat™ Urine ELISA (30143814)
- CatCombi ELISA (30146128)
- Adrenalin ELISA (30146129)
- Noradrenalin ELISA (30146130)
- Dopamine ELISA (30146131)
- MetCombi Plasma RIA (RE29111)
- Normetanephrine ELISA (RE59171)
- Metanephrine ELISA (RE59181)

Endocrinology

- Cortisol ELISA (RE52061)
- 17-OH-Progesterone ELISA (RE52071)
- 25-OH-Vitamin D ELISA (RE53041)
- DHEA ELISA (RE52221)
- Free Testosterone ELISA (DB52181)
- Serotonin Urine ELISA (30192571)
  Updated version of RE59121

Immunology

- soluble Interleukin-2-Receptor ELISA (30201813)
- Neopterin ELISA (RE59321)

Saliva Diagnostics

- 17beta-Estradiol Saliva Luminescence Immunoassay (RE62141), 96 tests
- 17beta-Estradiol Saliva Luminescence Immunoassay (RE62149), 960 tests
- 17beta-Estradiol Saliva ELISA (30121045)
- Cortisol Saliva Luminescence Immunoassay (30221150; IVDR Version of RE62111), 96 tests
- Cortisol Saliva Luminescence Immunoassay Bulk (30221151 ; IVDR Version of RE62119), 960 tests
- Cortisol Saliva ELISA (RE52611)
- DHEA Saliva ELISA (RE52651)
- Estriol High Sensitive Saliva ELISA (30121046)
- Progesterone Saliva ELISA (RE52281)
- Melatonin direct Saliva ELISA (RE54041)
- Testosterone Saliva ELISA (RE52631)
- Testosterone Saliva Luminescence immunoassay (30191568; IVDR Version of RE62031), 96 tests
- Testosterone Saliva Luminescence immunoassay (30191569 ; IVDR Version of RE62039.), 960 tests

ARE YOU LOOKING FOR IVDR COMPLIANT PRODUCTS?

Contact us for individual product information or orders!

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Learn more on
tecan.com/ivdr-clinical-labs

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