IVDR at Tecan.

QUESTIONS AND ANSWERS

TECAN.

The new In Vitro Diagnostic Regulation (IVDR)

The IVDR (Regulation (EU) 2017/746) is the new regulatory framework that affects all in vitro diagnostic medical devices on the European market.
It replaces the current EU Directive on in vitro diagnostic devices (IVDD 98/79/EC) and applied from May 26th, 2022. There is no way to automatically transfer IVDD-classified devices to the new IVDR – all devices must be transitioned to the new regulation's requirements.

IVDR certification timeline

Device class	Certified by May 26th	Risk level	Sell off* by May 26th
A (non-sterile)	2022	Low patient risk/low public health risk	2025
D	2025	High patient risk/high public health risk	2026
C	2026	High patient risk/moderate public health risk	2027
B and A (sterile)	2027	Moderate patient risk/low public health risk	2028

*Sell off means IVDs which have entered the supply chain before the end of their transition period may continue being made available until this date.

IVDR – Tecan is an early adopter

1. Established the IVDR project in February 2018
2. Part of trade associations and regulatory forums contributing to best practices in IVDR implementation
3. First IVD company undergo an IVDR QMS audit from Tecan‘s Notified Body (NB)
4. One of the first IVD companies to receive IVDR certification from Tecan‘s NB
5. Established a team of experts for IVDR implementation
6. Providing support and exchanging experience with partners
7. Seen by customers as on top of IVDR implementation

Why are most Tecan instruments not IVDR?

IVDR definition

'In vitro diagnostic medical device' means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens - including blood and tissue donations - derived from the human body, solely or principally for the purpose of providing information on one or more of the following* ...

IVDR out of scope

Article 1, section 3a excludes General Laboratory Use products (GP) from the application of IVDR, unless specifically intended for IVD use

IVDR classification

Annex VIII
1.2. If the device in question is intended to be used in **combination** with another device, the classification rules shall apply **separately** to each of the devices

Tecan intended use

Tecan's liquid handling platforms (in general):

- Are intended for general lab use
- Do not have a specific diagnostic purpose
- Can be used in clinical diagnostic environments
- Detailed intended use can be found in the corresponding manuals

Tecan's conclusion

- General laboratory use instruments may be used in a variety of laboratory environments according to their intended use
- In each environment, the individual laboratory is responsible for the validation of the instrument together with the specific reagents and labware used in the laboratory's application workflow or method
- General lab use platforms give flexibility to the user: from life science to **clinical diagnostics applications**

*For complete definition see the IVDR Article 2(2)

FAQs - Frequently Asked Questions

1 Can I still use my existing instrument?

YES, the installed base is not affected, and does not require any action

2 Can I use my existing Freedom EVOlyzer® with IVDR assays?

YES, but a (re)validation of your method and application might be required. Some Tecan reagents are validated to be used in open general lab instruments, e.g., Freedom EVOlyzer

3 Can I use an IVDR assay on Fluent® Automation Workstation or Freedom EVO® and EVOlyzer platform?

- YES, but a (re)validation of your method and application might be required
- The combined use of assays, process scripts and the Freedom EVO must be validated on site by each individual laboratory

4 Why is Tecan not launching an IVDR liquid handling instrument?

- Tecan liquid handling instruments are classified independently and are not currently required to transition to IVDR
- The current platforms can be used for clinical applications
- GP are out of scope of IVDR
- Would require a specific diagnostic intended use to fall under the purview of the IVDR
- Would increase instrument cost without adding additional benefits

5 Why Tecan does not have liquid handling instrument as IVDR if your competitors do have it?

- Tecan liquid handling instruments are intended for general laboratory use, without a specific IVD intended use. This makes them possible to be used in clinical environments in Europe
- Tecan also has IVDR platforms through its Partnering Business (PB), with partners as legal manufacturers

6 Can I upgrade my OEM platform to IVDR?

YES, we offer support to all our PB customers to bring their instruments to IVDR compliance

FAQs - Frequently Asked Questions

7 What can I say if an authority asks me about IVDR?

- Customers can refer to the legacy approach of an installed base and a validated system as long as there are no significant changes to the assay or the instrument
- Instruments installed after IVDR - refer to general lab rule on page 4

8 Can I use a RUO instrument for clinical diagnostics?

- This would be considered off label use
- Possible in an LDT environment, if the lab validates the whole system, and acts as legal manufacturer according to IVDR

9 What is the advantage of a GP platform?

- The GP platform is not validated/ connected to a specific clinical application and/or assay
- It can therefore be used for multiple applications after proper validation by the lab/user

10 Can I use an RUO kit for clinical diagnostics?

- Technically you can, but it is not recommended as this would be considered off label use
- Only possible in an LDT environment, if the lab validates the whole system and acts as legal manufacturer according to IVDR

11 Can I still use the IVDD product on a GP platform during the transition to IVDR?

- YES, as an end-user you can use up your stocks of IVDD products
- End customers can also purchase IVDD products until the end of the transition period

12 What does validation or revalidation/verification mean for clinical diagnostic labs?

- End customer has to assess and decide how much validation effort they have to make
- Efforts can range from a written statement to complete revalidation
- Tecan can support you on a case by case assessment

FAQs - Frequently Asked Questions

13 Can I keep reagents rental for Freedom EVOlyzer?

- YES – as long as the reagents from the contract are still available
- YES, the installed Freedom EVO is considered a legacy device, and can still be used

14 Which documents need to be generated by labs wanting to use LDT methods after May 26th, 2022?

The transition period for LDT (in house testing) is progressive (IVDR Article 5(5)).

- **From 26th May 2024:**
  - Quality Management system
  - compliance to EN ISO 15189
  - upon request: provide info on the use of device
  - public Declaration (similar to DoC)
  - technical documentation as per Art. 5 (5) (g)
  - review experience gained with clinical use of the device and corrective actions
- **From 26th May 2028:**
  In addition to all above, justification that the target patient group's specific needs cannot be (appropriately) met by equivalent commercial device

15 Which risk classes do Tecan reagents correspond to for clinical use?

Tecan reagents have different risk classes under IVDR – from class A to class D

16 How have you embraced the IVDR transition for a large reagent portfolio?

- Tecan engaged NB early:
  - scheduling quality system audits
  - clarifiying product classifications and groupings
  - developing a comprehensive submissions roadmap
- Throughout the entire process Tecan:
  - maintains communication with all internal and external stakeholders
  - manages expectations
  - follows up the timeline closely and
  - implements knowledge gained during the process

FOR ADDITIONAL INFORMATION ON IVDR,
please visit the Tecan IVDR home page DeckCheck:
www.tecan.com/ivdr-overview

REFERENCES

- Regulation (EU) 2017/746 – IVDR
- MDCG guidance 2020-16: classification rules

Tecan – Who we are

Tecan (www.tecan.com) helps to improve people's lives and health by empowering customers to scale healthcare innovation globally from life science to the clinic. Tecan is a pioneer and global leader in laboratory automation. As an original equipment manufacturer (OEM), Tecan is also a leader in developing and manufacturing OEM instruments, components and medical devices that are then distributed by partner companies. Founded in Switzerland in 1980, the company has more than 3,000 employees, with manufacturing, research and development sites in Europe, North America and Asia, and maintains a sales and service network in over 70 countries. Registered shares of Tecan Group are traded on the SIX Swiss Exchange (TECN; ISIN CH0012100191).

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