TECAN.

Are you IVD Ready?

Uncertainty in compliance is a growing business risk that clinical laboratories face worldwide

Clinical laboratories are constantly challenged by an increasingly complex regulatory environment. The FDA has now issued draft guidance on the regulation of Laboratory Developed Tests (LDTs), while previous guidance has also indicated concerns over use of research use only (RUO) products in clinical labs. Diagnostic laboratory businesses are facing the unknown as they are unclear over the regulation of their LDT's in future.

The European clinical industry also faces a looming transition with new legislation due to replace the current IVD directive 98/79/EC. This proposes changes in the scope of IVD, classification, conformity assessment and clinical evidence requirements. In Asia, the Chinese FDA has seen major regulation changes under a new leadership with ongoing uncertainty over interpretation.

The majority of the global diagnostics market is anticipating a regulatory transition leaving diagnostic business leaders with concerns over how to mitigate risk, get ahead of the regulation and STAY AHEAD!

In such uncertain times, choosing the right business partners is vital to minimizing risk, staying competitive and having confidence in your compliance. Tecan provides products and services that are compliant with clinical regulations around the world, with a globally distributed QA/RA organization to ensure an understanding of local needs. This is why over 80% of the top 30 diagnostic companies place their trust with Tecan. The same expertise that is available to our IVD partners are built into our Tecan products to support your lab of today and the future.

Economic value addition

Utilize our capabilities throughout your product life cycle

Business risk mitigation

Minimize your business risk by ensuring regulatory compliance using our products

- International QA/RA expertise
- Class 1 Medical devices, CE-IVD instruments
- Documented risk management
- Supply chain management

Improved time-to-result

Swiss high precision, reliable technologies manufactured under strict QSR guidelines

- ISO 13485
- 21 CFR Part 820
- Qualified supplier status
- Own 510k IVD assays

Reduced validation effort

Value-added services ensure cost savings for our IVD partners and end-customers

- Supporting 510k, PMA approvals
- Design and development services
- Application development with full design documentation

Trusted partner of choice

Over 80% of top 30 diagnostic companies rely on Tecan for their instrumentation

- Over 30 years experience with IVD products
- Sales and service support across 5 continents and 52 countries

Tecan – Who we are
Tecan is a leading global provider of laboratory instruments and solutions in biopharmaceuticals, forensics and clinical diagnostics. The company specializes in the development, production and distribution of automated workflow solutions for laboratories in the life sciences sector. Its clients include pharmaceutical and biotechnology companies, university research departments, forensic and diagnostic laboratories. As an original equipment manufacturer (OEM), Tecan is also a leader in developing and manufacturing OEM instruments and components that are then distributed by partner companies. Founded in Switzerland in 1980, the company has manufacturing, research and development sites in both Europe and North America and maintains a sales and service network in 52 countries. IBL International is a major player in the development and distribution of in vitro diagnostic assays for special and rare indications for use in research and routine diagnostic laboratories. IBL International is a Tecan Group company.

Australia +61 3 9647 4100 **Austria** +43 62 46 89 33 **Belgium** +32 15 42 13 19 **China** +86 21 220 63 206 **Denmark** +45 70 23 44 50 **France** +33 4 72 76 04 80 **Germany** +49 79 51 94 170
Italy +39 02 92 44 790 **Japan** +81 44 556 73 11 **Netherlands** +31 18 34 48 17 4 **Singapore** +65 644 41 886 **Spain** +34 935 95 2531 **Sweden** +46 8 750 39 40
Switzerland +41 44 922 89 22 **UK** +44 118 9300 300 **USA** +1 919 361 5200 **Other countries** +43 62 46 89 33

www.tecan.com/clinicalsolutions

398818 V1.0 07-2015, 30102283