Keep flowing forward

Be prepared for *In Vitro* Diagnostic Medical Device Regulation

Discover the simplified walkaway
integrated clinical flow cytometry solution

BD

What is *In Vitro* Diagnostic Medical Device Regulation?

The European *In Vitro* Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746 came into effect on 26th May 2017 and replaces the European *In Vitro* Diagnostic Medical Device Directive (IVDD) 98/79/EC.

EU-IVDR is not only an update of the IVD Directive, but an in-depth change of the rules applicable for placing *in vitro* diagnostic medical devices on the market. This new regulatory framework impacts manufacturers of in vitro diagnostic medical devices (IVDs) and health institutions that use laboratory developed tests (LDTs).

Both companies and labs must meet enhanced requirements to support the safety and performance of their devices, ultimately aiming to ensure a high level of safety and health and protection of health for patients and users.

IVDR (EU) 2017/746

- Sets high standards for the safety and traceability of In Vitro Diagnostic Medical Devices (IVD).
- Enhances harmonisation across member states in EU.

Impact on Diagnostic Laboratories

- Laboratory developed tests (LDT) are in scope of IVDR, with requirements and conditions to be met.
- Could lead to additional complexities and costs.

Key IVDR Article 5(5) milestones; impact to laboratories

Journey towards IVDR commences

- Five year transition period

Date of Application

- Article 5(5) first & last paragraph & a*
- Annex 1: GSPR

Milestone with significant impact

- Article 5(5) b - i, except d**

Full Application:

- Complete transition to all IVDR requirements***

*Article 5(5) a: transfer of devices

** Article 5(5) b: QMS, Article 5(5) c: EN ISO 15189 compliance or where applicable, national provisions, Article 5(5) e: Information to competent authority, Article 5(5) f: Public declaration, Article 5(5) g: documentation Class D (member states may extend to class A, B or C), Article 5(5) h: Manufacturing in accordance with point g, Article 5(5) i: Review clinical experience

*** Including Article 5(5) d: Justification for use

IVDR impact on laboratories

Health Institutions (HI), like laboratories*, can only use LDTs if all the requirements of the entire IVD Regulation (EU) 2017/746 are met or the HI meets all the conditions of Article 5(5), in that case they are exempt from having to meet IVDR requirements in full and the LDT only needs to be compliant with the relevant general safety and performance requirements (GSPRs) in Annex I.

The 3 main chapters in Annex I;

Chapter I

General requirements

Chapter II

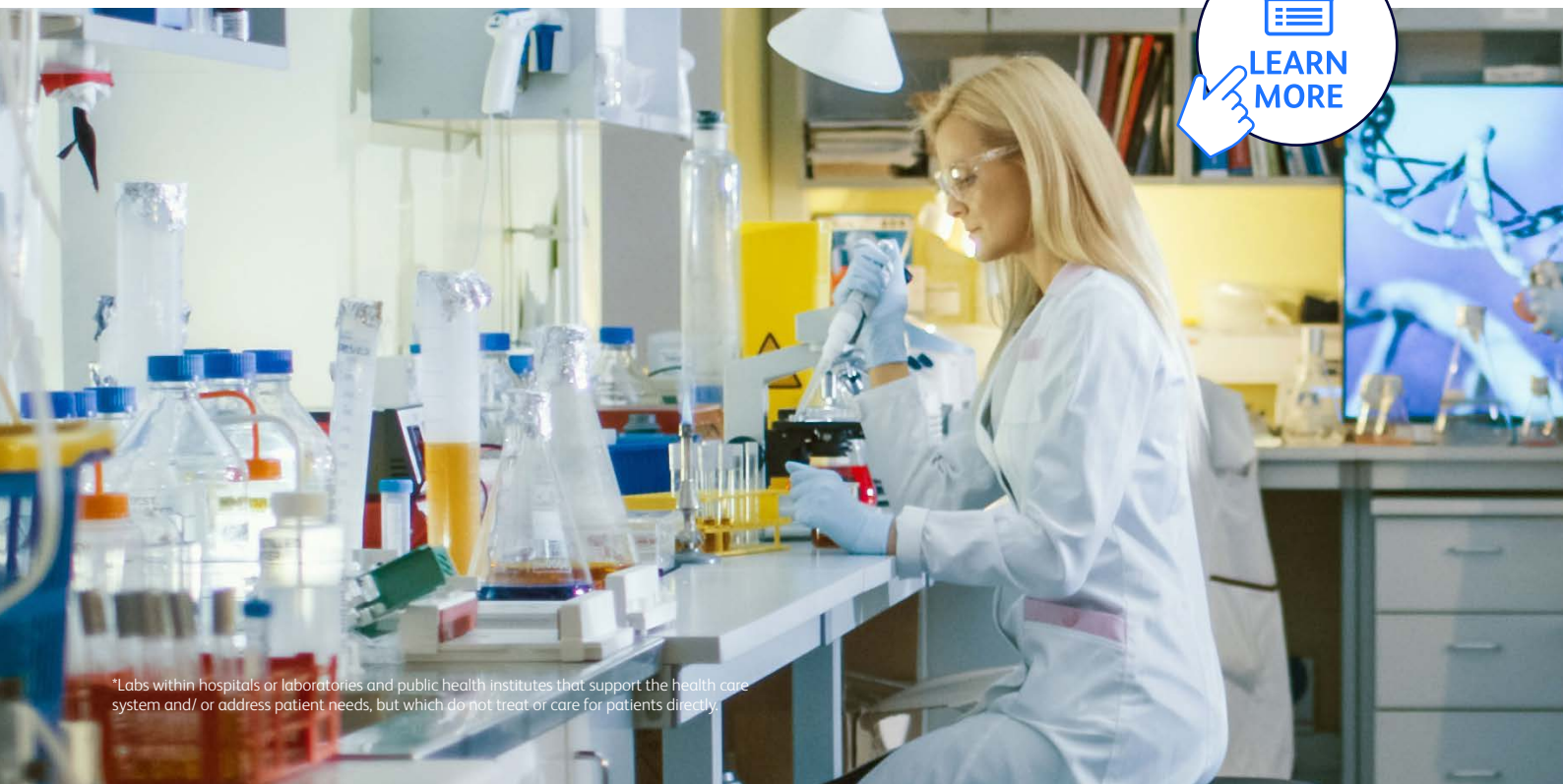
Performance, design and manufacture

Chapter III

Information supplied with the device

In addition, IVDR only allows the manufacture and use of an LDT if there is no equivalent CE-IVD device on the market, which would likely be the case in rare diseases, or if the HI demonstrates that a target patient-group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent CE-IVD device.

Labs have had to demonstrate compliance to Article 5(5), except (b) to (i), and Annex I since 26th May 2022. From 26th May 2024, labs also need to show conformity to Article 5(5) (b) to (i), except part d. The deadline for Article 5(5) part d, which covers the justification for use of an LDT, and therefore fulfilment of a full IVDR application is 26th May 2028. Labs will need to ensure significant dedicated resource and budget are allocated to ensure compliance with all the requirements of the EU-IVDR.[1]



*Labs within hospitals or laboratories and public health institutes that support the health care system and/ or address patient needs, but which do not treat or care for patients directly.

Key requirements addressing LDTs within health institutions as per Article 5(5) of the EU-IVDR

- Device manufactured and used within a Quality Management System framework
- Lab EN ISO 15189 accredited or alternate national provisions
- LDT comply with General Safety and Performance Requirements
- Review clinical use, take corrective actions where necessary
- Manufacturing, design and performance documentation
- Make declaration of conformity publicly available

NOTE: The above lists just a few of the conditions as outlined in Article 5(5)

Please note that ALL conditions as outlined under Article 5(5) need to be met for the exemption to apply

A complete solution that simplifies compliance, automation, standardisation and quality

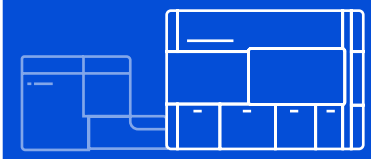
Simplify your path to IVDR with our integrated walkaway clinical flow cytometry sample preparation and acquisition solution that includes reagent cocktailing and onboard washing and supports both IVD and user-defined workflows. Automate and standardise your clinical flow cytometry workflows, with features that support reproducibility, quality, consistency with a fully traceable workflow and automated electronic audit trail that supports validation and quality of your flow cytometry tests. Whether you work in a haemato-oncology, immunology or transfusion and transplantation lab, BD have one integrated solution that will enable you to flow forward.

Our integrated clinical solution is supported by a broad and continuously expanding portfolio of single-colour and multi-colour CE-IVD reagents and ready to use kits.

One integrated walkaway sample-to-answer system

1. Sample preparation

BD FACSDuet™ System*



- IVD & user-defined assays
- Onboard washing
- Reagent cocktailing
- Traceability & audit trails

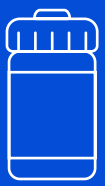
2. Sample acquisition

BD FACSLyric™ Flow Cytometer

- Simplified, standardised workflows for IVD and user-defined assays
- Automated set up & compensation
- Assay portability

3. Reagents

Single colour antibodies and multi-colour kits



- A broad and expanding CE-IVD reagent portfolio
- Ready-to-use reagent solutions for a range of clinical applications

4. Analysis

BD FACSuite™ Software

- IVD assay modules with automated gating
- Flexible user-defined assays
- Traceability & audit trails

5. Result reporting

BD FACS™ Workflow Manager

- Seamless bidirectional integration
- Data security & integrity

* BD FACSDuet™ Sample Preparation System and BD FACSDuet™ Premium Sample Preparation System

Resources

- Further information on how the BD solution can simplify your path to IVDR
- BD IVDR compliant portfolio
- The Biomedical Alliance in Europe IVDR task force
- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- MDCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746. January 2023
- European Commission Fact Sheet. Helping the transition to the new rules on medical devices and in vitro diagnostics 2024.
- European Commission Fact Sheet for healthcare professionals and health institutions. Medical devices: change of legislation. What you need to know. 2020.

References

1 Dombrink et al. Critical Implications of IVDR for Innovation in Diagnostics: Input From the BioMed Alliance Diagnostics Task Force. HemaSphere (2022) 6:6(e724).

CE BD FACSDuet™ Sample Preparation System, BD FACSDuet™ Premium Sample Preparation System, BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ applications are in vitro diagnostic medical devices bearing a CE mark.

CE 2797 BD Single-Colour Antibody reagents are in vitro diagnostic medical devices bearing a CE mark and are CE certified by BSI Group The Netherlands B.V. (Notified Body Number = 2797).

Disclaimer: This document highlights only a few elements for consideration. Please refer to the complete IVDR (EU) 2017/746 document for full details

BD Flow Cytometers and BD FACSDuet™ Sample Preparation System are Class 1 Laser Products.

BD Europe, Terre Bonne Park - A4,
Route de Crassier 17, 1262 Eysins, Switzerland

bdbiosciences.com

BD, the BD Logo and all other trademarks are property of Becton, Dickinson and Company.
© 2024 BD. All rights reserved. BD-116000 (v1)