CHARTER

IVD industry - Medical laboratories

beMedTech December 2023

INTRODUCTION

In vitro diagnostics (IVDs) are medical devices for the in vitro examination of specimens derived from the human body with the aim of providing information on one or more of the following:

(a) concerning a physiological or pathological process or state;

(b) concerning congenital physical or mental impairments;

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions; (f) to define or monitoring therapeutic measures.

Recipients for specimens are also considered medical devices for in vitro diagnostics.

IVDs play a crucial role in the decision-making process of doctors. They are therefore one of the most important decision pillars in healthcare in prevention, (early) diagnosis, prognosis, in setting the right therapy and monitoring.

IVD tests performed in medical laboratories include clinical biology, pathological anatomy and genetic analyses. 60-70% of all medical decisions are based on the results of laboratory tests using IVDs[1-2].

The first version of this charter between the medical laboratories and the IVD industry was published in 2016[3]. It answered many questions from the medical laboratories and was the result of intensive consultations by the IVD industry with the authorities and clinical biologists in Belgium.

However, the healthcare sector is constantly evolving: new laws are released, technology keeps improving and the needs and wishes of laboratories change with it. After seven years, the time has come to refresh the charter and adapt it to the new situation.

The objective of this charter remains unchanged. It aims to build a partnering relationship between medical laboratories for clinical biology, pathological anatomy and centres for genetics, on the one hand, and the IVD industry, on the other (referred to below as 'companies', and including manufacturers, authorized representatives, importers as well as and mainly distributors), based on a mutual understanding of the needs and obligations as well as safe and effective use of the devices.

Together, we all strive for sustainable healthcare and an increased quality of life for patients. This is only possible through a commitment to continued investment in IVDs to ensure quality products and services. Here, it is important that the entire chain, from design and production to distribution and execution of tests in the laboratories, is safeguarded and that both companies and laboratories respond together to changing regulations and context.

CONTEXT: LAWS, REGULATIONS AND INTERNATIONAL STANDARDS

European regulations[4-5] stipulate that all in vitro diagnostic medical devices must be CE marked to enter the European market. Products are CE-marked if a company can demonstrate that its products meet the general safety and performance requirements of the European IVD regulations, using the necessary technical documentation.

Companies' quality management system

The companies subscribing to this charter can guarantee their processes as well as the quality of the services and products provided by implementing a quality system that is demonstrably compliant with the **ISO 9001[6] and/or ISO 13485[7] standard**. By complying with the requirements established in the above-mentioned standard, the companies demonstrate their ability to supply all products and devices - within the medical technology industry and related services - thus consistently meeting the requirements of the laboratories and all applicable legal requirements.

The companies' competence is reflected in a well-founded policy on employee competence, chain traceability, customer communication, vigilance as well as distribution of products and services.

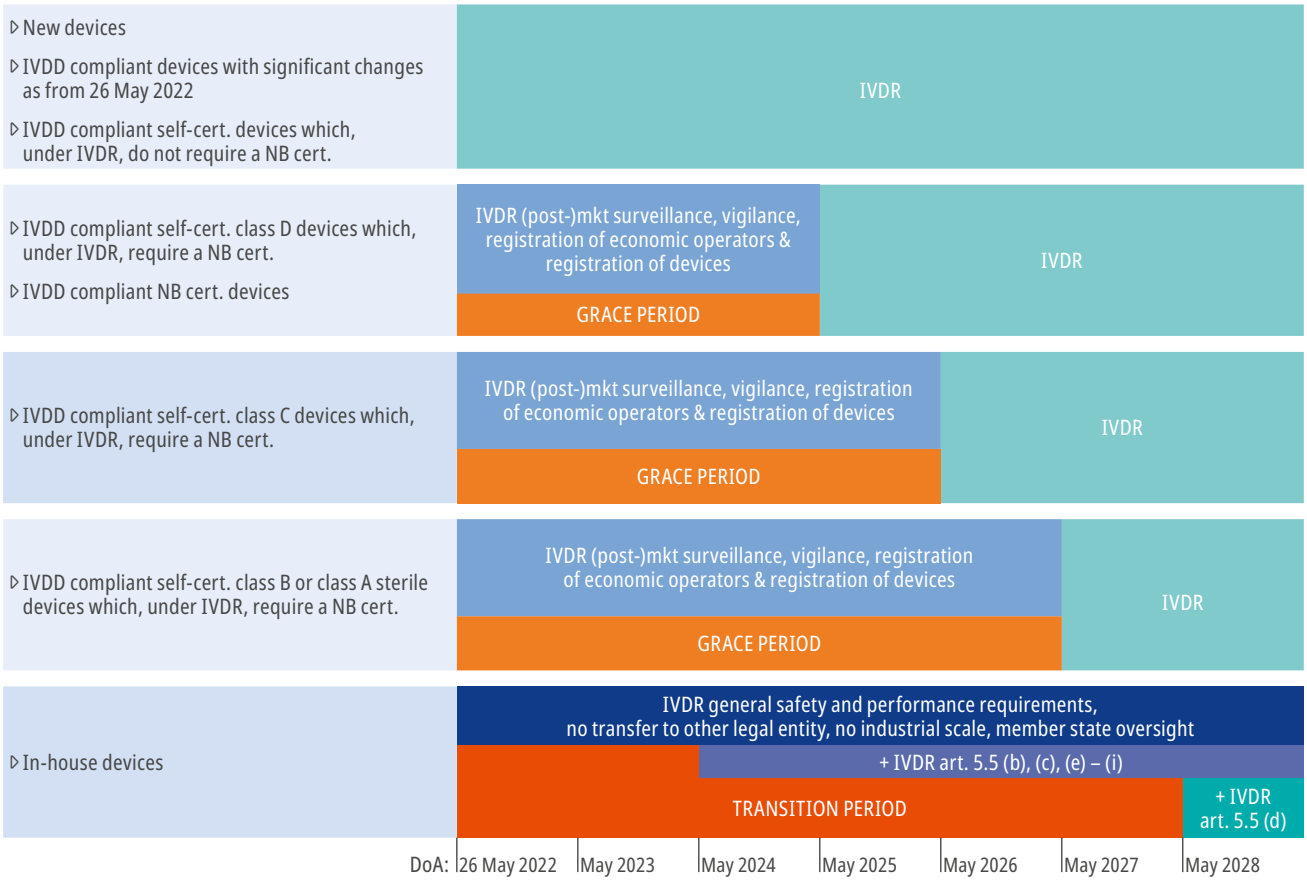
Quality management system of medical laboratories

The requirements of medical laboratories are determined by current laws and regulations. For the clinical biology and pathological anatomy laboratories, the practice guidelines[8-9] are a practical implementation of the published royal decrees on the accreditation of the above laboratories[10-11]. All acknowledged medical laboratories have a quality management system as described in the quality manuals in accordance with the practice guidelines. The practice guidelines are inspired by the ISO 15189 standard[12], which defines quality and competence requirements for the accreditation of medical laboratories. The implementation of a quality system in accordance with this standard is a requirement for all labs with BELAC accreditation or that wish to obtain it.

Since IVD companies do not provide laboratory services themselves, ISO 15189 requirements do not apply to manufacturers, importers or distributors of IVDs. IVD manufacturing, importing or distributing companies are covered by other quality management system standards, namely ISO 13485 or ISO 9001. However, the IVD industry can be a partner for laboratories in their ISO 15189 accreditation.

Requirements of the IVD directive 98/79/EC, Belgian IVD legislation and the new IVD regulation 2017/746 and its amendment

European legislation ensures the safety and efficacy of medical devices and facilitates patient access to devices on the European market. To keep up with advances in science and technology, the new European IVD Regulation 2017/7464 (IVDR) replaces the existing European IVD Directive 98/79/EC5 (IVDD), from 26 May 2022. However, there is a transitional provision that was extended in an amendment[13], allowing most devices with their CE declaration of conformity under the IVDD to be placed on the market and/or put into service during an additional time frame ('grace period'), depending on their appropriate risk class under the IVDR. According to the recent amendment[14], devices that have been legally placed on the market before the end of the grace period can continue to be made available on the market without any legal time restriction. There is also a transitional provision for certain requirements under IVDR Article 5.5 for healthcare facilities (laboratories) that manufacture and use 'in-house assays'. All this is summarised in the figure below.



Grace period: some IVDs may still (temporarily) remain in compliance with IVDD even after the DoA of 26 May 2022. The IVDR makes this possible by means of Article 110 (3) (the so-called "grace period"). The grace period allows economic operators to place on the market/put into service IVDD compliant devices for a certain period of time after the DoA of the IVDR.

In-house devices: devices manufactured and used within the same health institution.

DoA: date of application.

Mkt: market.

New: new devices on the market that have not been certified or self-declared for conformity under the IVDD.

Cert.: certified / certificate.

NB: notified body.

Devices legally placed on the market before the end of the grace period **can be made further available on the market** without a legal time restriction.

The new regulation contains a series of important improvements to modernise the current system and, in addition, calls for ~80% of IVD conformity assessments with now stricter requirements to be done by recognised notified bodies. Moreover, the regulation no longer needs to be transposed into Belgian law, whereas the European IVD Directive did[15]. The competent authority in Belgium is the Federal Agency for Medicines and Health Products (FAMHP)[16], to whom notification must be made when a medical device is placed on the market.

COMMITMENTS FROM THE COMPANIES:

The companies, which have subscribed to this charter, undertake to support medical laboratories in their pursuit of quality, with the following elements:

1. **Compliance with laws and regulations:**
   - Compliance with Belgian legislation[15,17-18] on IVDs and European regulation IVDR[4] with different criteria and transitional provisions according to the scheme on previous page
   - Meeting its registration obligation as set out by the FAMHP[16,19] and adhering to good distribution practices[20]
   - Following the Mdeon[21] rules and beTransparent[22] rules (Royal Decree implementing the Sunshine Act[23]).
2. **Qualifications:**
   - Perform and document installation and operational qualification (IQ and OQ).
3. **Training:**
   - Technical staff is competent based on appropriate education, training or experience. This can be demonstrated through an ISO certificate or - only if this is not available - through a declaration of competence.
4. **Documentation:**
   - Timely provision of appropriate and updated documentation (CE documents, leaflets, safety data sheets, manuals, reference values, release notes prior to software updates, important product information, etc.).
5. **Maintenance and intervention:**
   - Maintenance work and technical interventions are carried out and documented as required
   - Performing checks to demonstrate proper instrument operation after maintenance or technical intervention
   - Provide with a helpdesk or point of contact where labs can go for questions and/or technical support.
6. **Protection of personal data:**
   - Comply with applicable regulations on personal data protection[24-25]
   - Responsibilities for data processing and management will be established between the two parties, in the form of a confidentiality agreement and data processing agreement.
7. **Cybersecurity:**
   - Taking appropriate technological and organisational measures through IT security to help reduce the risk of cyber attacks and data breaches with the aim of preventing them.
8. **Code and ethics:**
   - Adhere to the beMedTech code[26], to live up to the highest degree of ethical responsibility in carrying out their activities.
9. **Vigilance:**
   - Customer notifications, field safety notices, field safety corrective actions and recalls will be communicated appropriately and timely.
10. **Prevailing lab rules:**
    - Reasonably respect the rules of conduct, security, confidentiality and house rules in force within the laboratory.

EXPECTATIONS TOWARDS THE LABORATORIES:

What do companies expect from medical laboratories (labs)?

1. The lab will use and maintain the device like a good family man and according to the instructions for use.

2. The lab informs the company of the applicable conduct, security, confidentiality and house rules.

3. The lab will reasonably enable the company's staff to perform services by providing it with access to the system and equipment. This includes, if necessary, physical access to the workstations where the system is installed, ensuring security.

4. The lab will notify the company after the occurrence of any malfunction or defect related to the devices, products and services through the applicable specified procedure.

5. The lab should communicate changes in the configuration of the system to the company.

6. The lab is responsible for backup, monitoring and security procedures regarding the system and the data stored on it. The guidelines for backup and security procedures are provided by the company.

7. The lab appoints a referent: permanent contact person within the lab for a particular instrument or system. This person is trained on the system and liaises with the company for service and repair. Records should be kept up to date. It is also desirable to provide a backup.

8. The lab designates a point of contact for materiovigilance[19]. The data should be kept up to date. It is also desirable to provide a backup. The lab should provide an acknowledgement of receipt of reported vigilance information, if requested by the company.

9. The lab is responsible for doing the performance qualification (PQ).

10. The lab will work according to the applicable regulations around personal data protection[24-25]. Responsibilities for data processing and management will be established between the two parties, in the form of a confidentiality agreement and data processing agreement. If possible, no personal, sensitive information will be provided.

11. Disposable packaging is disposed of according to applicable guidelines.

12. Although test results from an IVD can play a role in making a medical decision, only authorised healthcare providers can make medical decisions. The lab will never ask the company to make any medical decisions.

SIGNATORIES:

This charter has been signed by the following beMedTech members:

Abbott – A Promise for Life
AGENDIA – MAMMAPRINT – BLUEPRINT
AIDIAN
Axonlab – connecting ideas
BD – Advancing the world of health
Binding Site
BIO-RAD
BIOCARTIS
BIOMÉRIEUX
Cepheid – A better way.
DiaSorin
EXACT SCIENCES
FUJIREBIO
illumina
lumiraDx
A.MENARINI diagnostics
QIAGEN
QuidelOrtho
Roche
sebia benelux
SIEMENS Healthineers
Stago
sysmex
ThermoFisher SCIENTIFIC
Volition
werfen

This charter was also endorsed by:

The Commission for Clinical Biology

The Commission for Pathological Anatomy

COLLEGE GENETICS
The Belgian College of Genetics and Rare Diseases

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6. EN-ISO 9001:2015 Quality management systems - Requirements.
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8. Royal Decree of 3 December 1999 on the approval of clinical biology laboratories by the Minister to whom Public Health belongs:
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