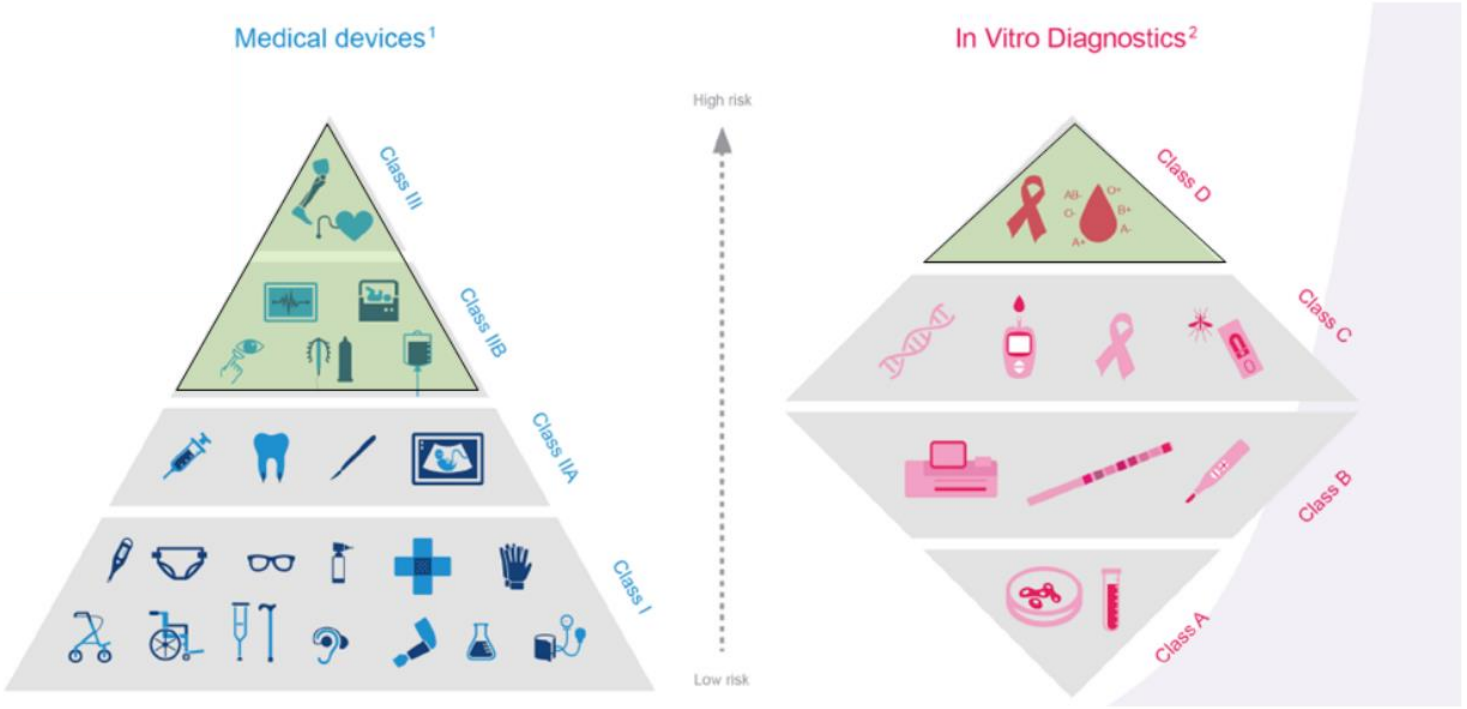
IVDR 2017/746

IVD-regulation: laboratory perspectives

UZ Leuven | Herestraat 49 B - 3000 Leuven | www.uzleuven.be tel. +32 16 33 22 11

UNIVERSITY HOSPITALS LEUVEN

Medical devices & In vitro diagnostics medical devices



MDD -> MDR

IVDD -> IVDR

Software

Impact of the IVDR on key stakeholders

For the public/patients

- Safer devices and more transparency

For manufacturers/distributors

- Obligation to generate sufficient evidence that product is safe and performing as intended
- Following up the safety and performance of the product when on the market (internal processes)
- More public/media scrutiny of public product information

For notified bodies

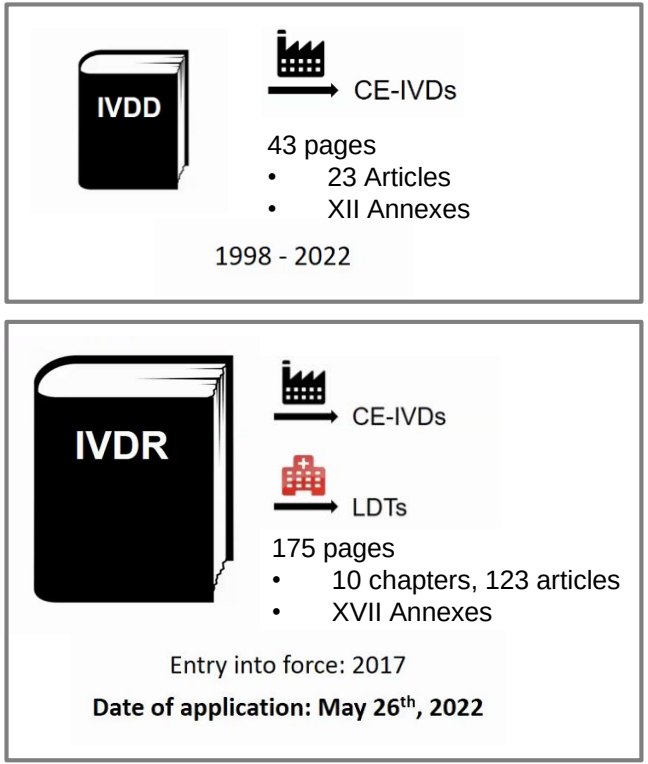
- Stricter requirements concerning expertise and processes, more oversight
- Some will go out of business -> 'Traffic jam' at Notified Bodies?

For health institutions

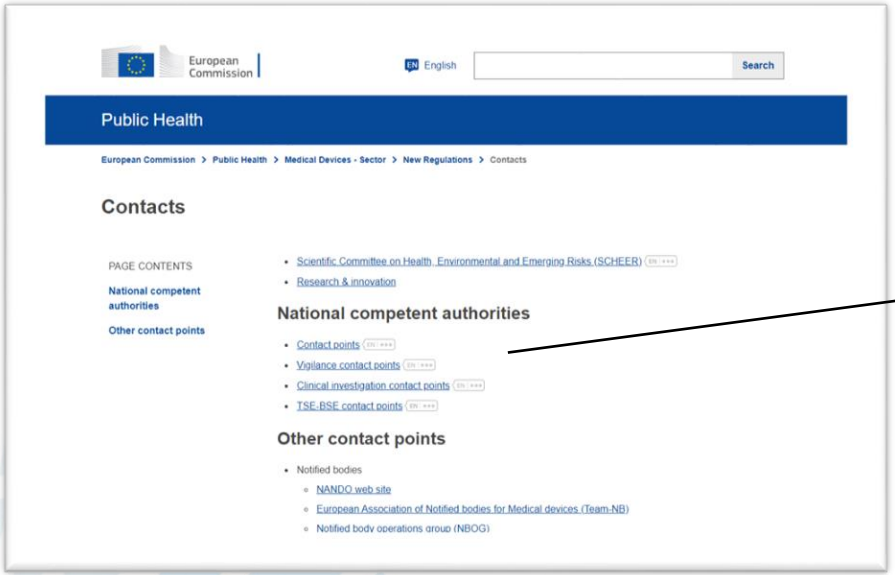
- There will be stricter standards for the development of in-house tests
- Laboratories may be forced to use commercial IVDs instead of in-house developed tests
- Regulation also applies to software (e.g. open source software that is used in bioinformaticpipelines)

IVDR (5 April 2017)

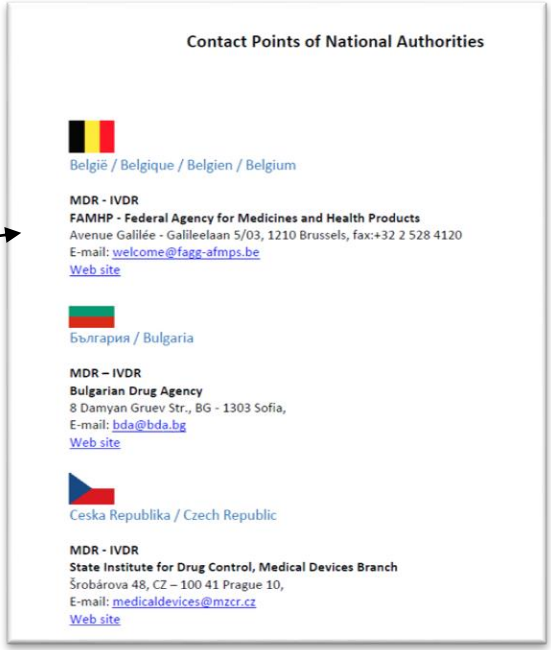
- **European regulation,** to be implemented in each EU country **'as such'**, not only for CE-IVDs but also for LDTs (IH-IVD)
- In addition to the regulation, there will be EU guidelines / interpretation documents
- There is a **separate implementation law** for each country,
  - With explanation who is competent authority,
  - Clarify their competence and national interpretation (where possible)
  - Name of competent authority



Competent authority (CA) (monitoring of LDTs / IH-IVD)



https://ec.europa.eu/health/medical-devices-sector/new-regulations/contacts_en



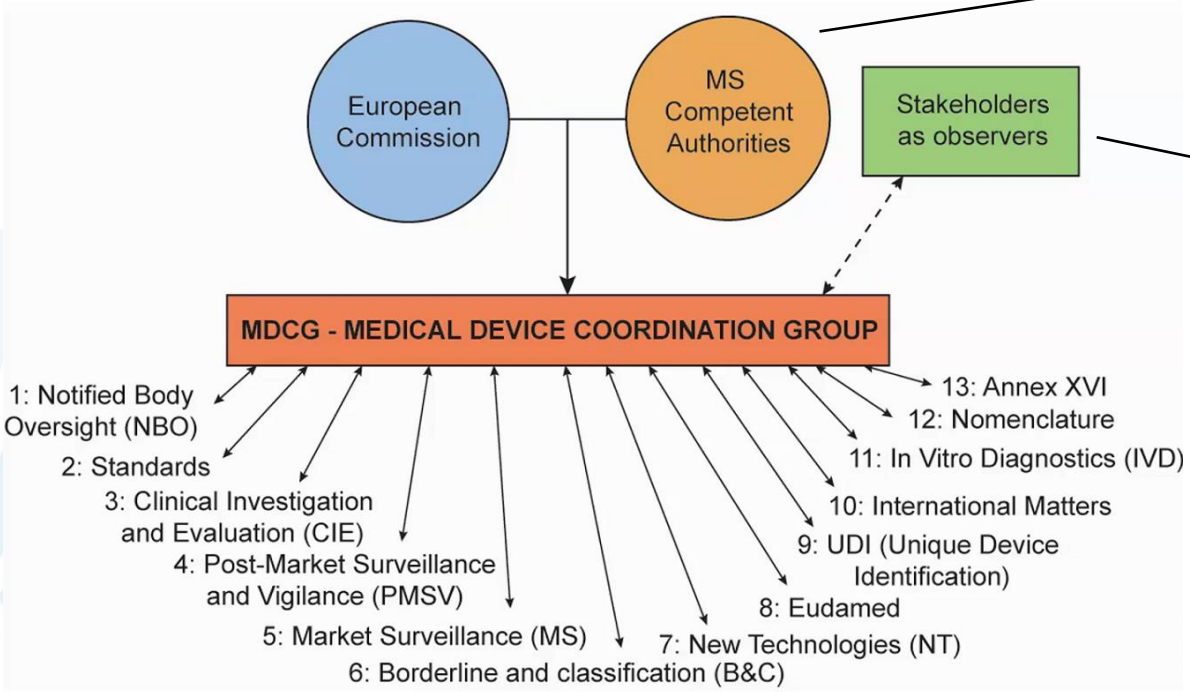
Important to build good contacts with the national competent authority !

Which organisations are involved?

1. **Competent authority** (CA) (monitoring of LDTs / IH-IVD)
2. **Notified bodies (NB)** for CE-IVD certification
3. **EU Reference laboratories for IVDR** (EU Joint Research Centres) always for Class D testing
4. **IVDR Expert group** for monitoring/recommendations of reports NB (EU call for experts)
5. **EU commission** (DG Grow and Sante - general supervision and coordination)

UZ LEUVEN

Organisations involved in the implementation of MDR/IVDR



BE - Competent authority

fagg

Eg, EFLM,
BioMed Alliance
(EFLM, ESP, **ESHG,**
ESCMID, …)

Guidelines and
interpretation
documents

UZ LEUVEN

INHOUD

- MDCG work in progress
- Borderline and Classification
- Class I Devices
- Clinical investigation and evaluation
- COVID-19
- Custom-Made Devices
- EUDAMED
- European Medical Device Nomenclature (EMDN)
- Implant cards
- Importers & Distributors
- In Vitro Diagnostic medical devices (IVD)
- New technologies

In Vitro Diagnostic medical devices (IVD)

Reference	Title	Publication
MDCG 2022-6 EN	Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR	May 2022
MDCG 2022-3 EN	Verification of manufactured class D IVDs by notified bodies	February 2022
MDCG 2022-2 EN	Guidance on general principles of **clinical evidence** for In Vitro Diagnostic medical devices (IVDs)	January 2022
MDCG 2021-22 EN	Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies, in context of the **consultation of the expert panel** referred to in Article 48(6) of Regulation (EU) 2017/746	August 2021
MDCG 2021-4 EN	Application of **transitional provisions** for certification of **class D** in vitro diagnostic medical devices according to Regulation (EU) 2017/746	April 2021
MDCG 2020-16 Rev.1 EN	Guidance on **Classification Rules** for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	January 2022

UZ LEUVEN

Ongoing guidance development and deliverables of MDCG Subgroups –April 2022*

**This is not an exhaustive list of ongoing work performed by MDCG Subgroups*

Scope	Group Deliverables	Consult prior to MDCG**	Planned MDCG Endorsement	Additional Comments
*** Stakeholders are observers in 13 MDCG subgroups and are consulted on a regular basis; further to that other MDCG subgroups are consulted as indicated*				
11. *In Vitro* Diagnostic Medical Devices (IVD)				
IVDR	*SSP (Summary of Safety & Performance) template*	CIE	2022	Template in development
IVDR	*Qualification of assays used in clinical trials of medicinal products*	N/A	2022	In collaboration with competent authorities for medicinal products
IVDR	*In-house devices*	MS	2022	Joint with Market Surveillance MDCG sub-group, draft in preparation
IVDR	*Analysis of IVDR in context of hypothetical scenarios of an urgent response to a health crisis*	N/A	2022	In progress
IVDR	*Performance study application/notification form*	CIE	2022	Template in development
IVDR	*Guidance on significant changes referred to in Article 110(3) of the IVDR*	NBO	2022	With reference to MDCG 2020-3
IVDR	*Guidance on application of IVDR requirements to legacy devices and those placed on the market before DoA*	NBO, PMSV, MS	2022	With reference to MDCG 2021-5
IVDR	*Minor revision of MDCG 2021-22 – Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies*	N/A	2022	Addition of notes, based on experience collected so far

UZ LEUVEN

ESHG is a member of Biomed Alliance

Activities with BioMed Alliance

- Reinforcing importance of IH-IVD and monitoring requirements of EU IVDR 2017/746
- Mini Survey – open paper
- Feedback on MDCG guidelines
- Interaction with the European Commission (stakeholder)

Impact of IVDR for Genetic testing labs

HemaPolicy
Open Access

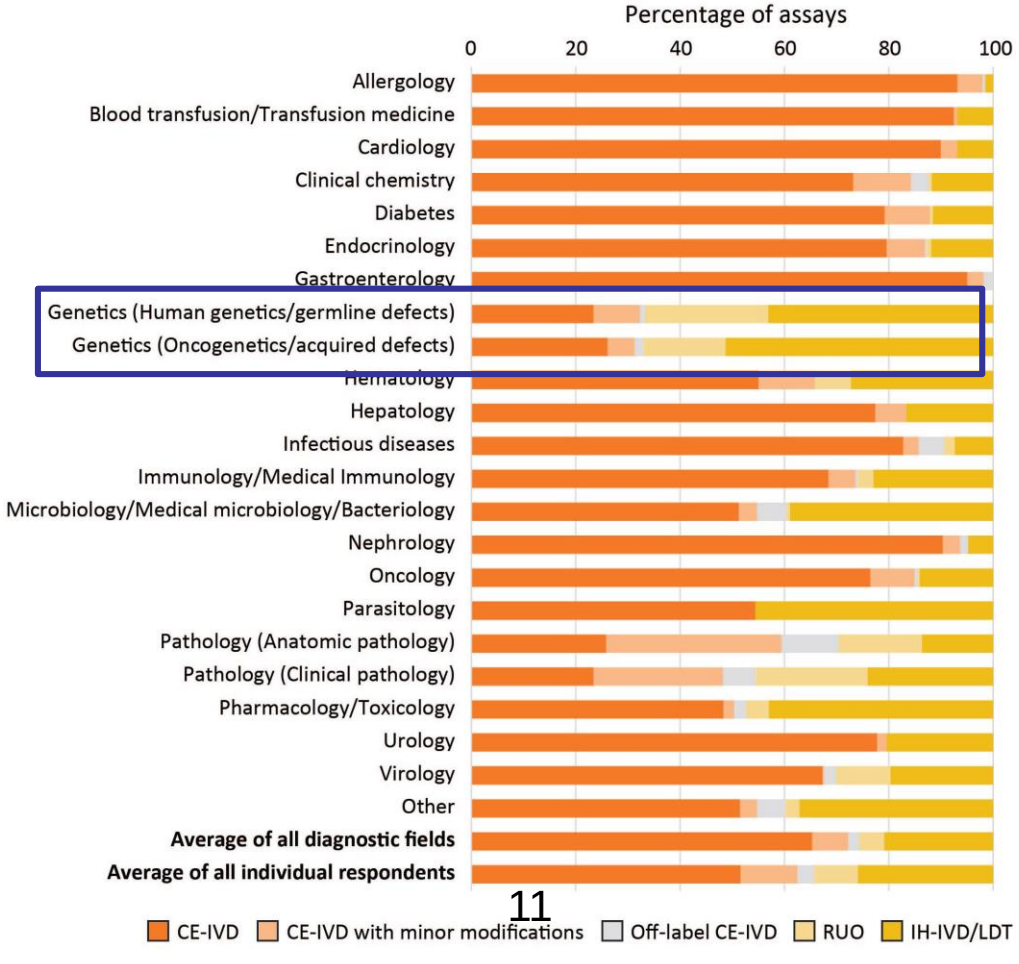
Critical Implications of IVDR for Innovation in Diagnostics: Input From the BioMed Alliance Diagnostics Task Force

Isabel Dombrink[1–3], Bart R. Lubbers[1,4,5], Loredana Simulescu[1], Robin Doeswijk[1,5], Olga Tkachenko[6], Elisabeth Dequeker[1,7,8], Alan G. Fraser[1,9], Jacques J. M. van Dongen[1,4,5,10,11], Christa Cobbaert[1,12,13], Monika Brüggemann[1–3,5], Elizabeth Macintyre[1,5,14]

Hemasphere. 2022 May 20;6(6):e724

>80 – 90 % of the test are

- ***in-house IVD test with no CE-IVD alternative***
- ***Or in-house IVD test with a CE-IVD but not comparable***



Timeline

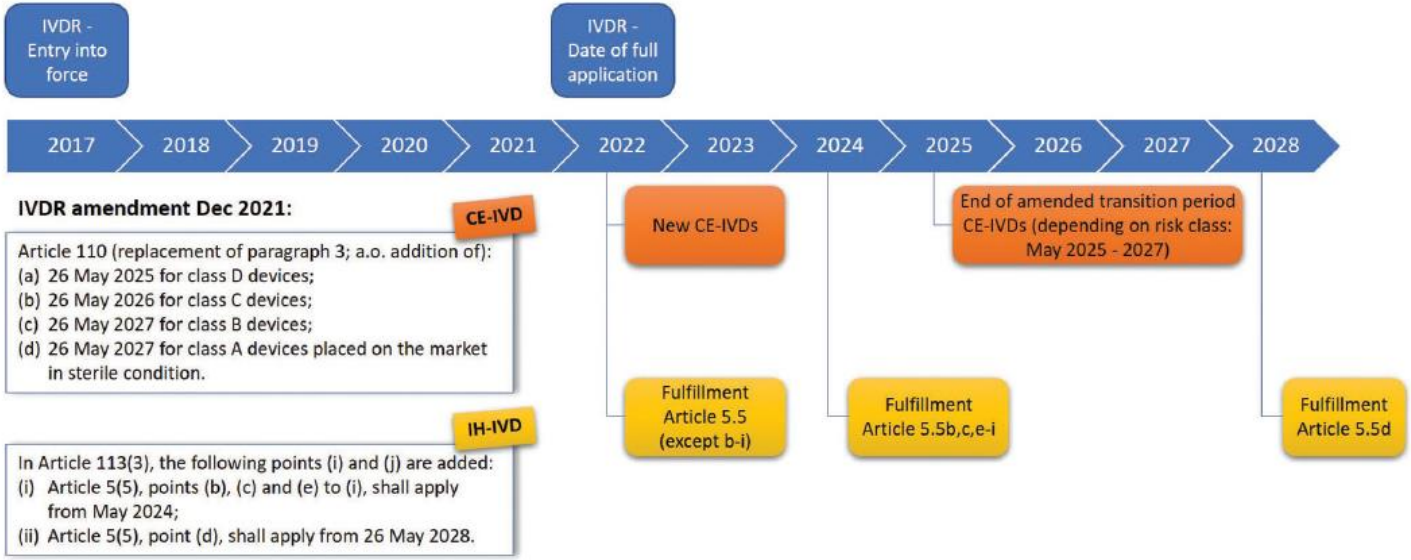


Figure 3. Timelines for revised phased IVDR implementation. The General Safety and Performance Requirements specified in Annex I as well as Article 5.5 (with the exception of 5.5b to i) are not mentioned in the amendment and are, as such, applicable from May 2022. CE-IVDs = CE marked in vitro diagnostics; IH-IVDs = in-house in vitro diagnostics; IVDR = Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

"IVDR – Beneficial or just an expensive straight-jacket?"

June 22, 2022, 10:00 – 16:30 hrs

The **new IVD EU regulation (IDVR 2017/746)** has major implications on the use, availability and associated costs of in vitro diagnostic tests. But on the other hand, it also builds in many ways new assurance points to improve and monitor the quality of our diagnostic services.

To help laboratories prepare for the IVDR, including compliance with IVDR requirements for in-house devices, the ESHG is hosting a free of charge full-day webinar on IVDR, providing the basics and latest updates on implementation, as well as tips and tricks for working towards compliance.

During these webinar presentations we invite speakers from the EU Commission, Notified Bodies, Compent authorities, national IVDR working groups, lab people working on the implementation of the IVDR will share their knowledge and experience.

Program – 8 speakers & discussion sessions

- Introduction on IVDR
- Role of different organisation: EC, CA, NB, Reference labs, observers
- IH-IVD's and hospital exemption
- MDCG guidelines and the guideline of in-house devices

Participation is free of charge, registration is necessary !

Who should attend:
clinical Scientist, Lab Technicians, Lab Managers, Quality Managers, Lab Directors, Bioinformaticans

UZ LEUVEN

ESHG / Eurogentest will set up a TF or working group

- Call for persons already active nationally with IVDR in the genetic field

- Which countries already have a national working group?

Send all information to: Els.Dequeker@uzleuven.be