IVDR 2017/746

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Quite a **challenge** for **new tests for "rare diseases"** to preserve the final purpose of the regulation

►B 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

(Text with EEA relevance)

(OJ L 117, 5.5.2017, p. 176)

Call for embedding an incubation period

Prof dr E Dequeker, Belgium
Representative for the ESHG

IVDR 2017/746 (May, 26th 2022) – *Harmonization*

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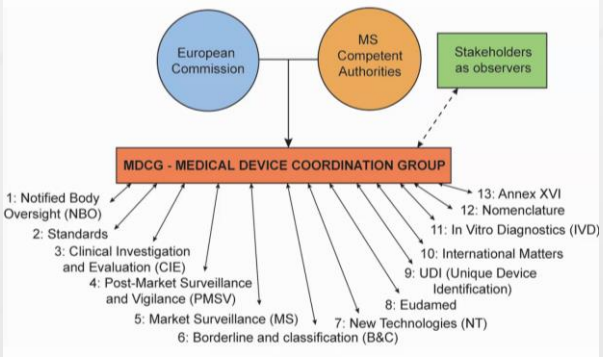
- **European regulation**
  - CE-IVD & In-house (IH)-IVD
  - Industry & Health Institution

- **EU guidelines / interpretation documents – MDCG**



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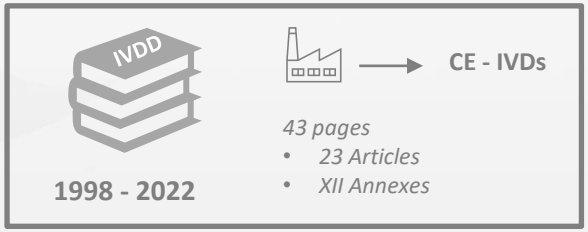
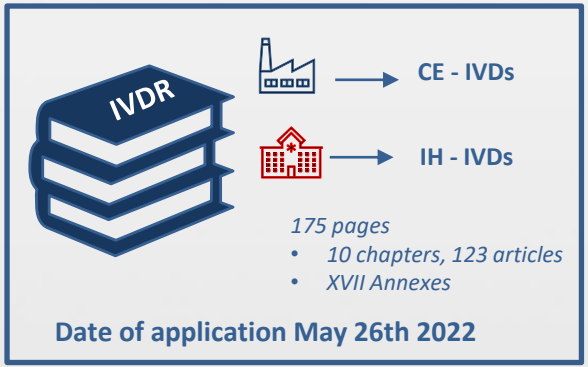
MDCG 2022-15,
MDCG 2022-22 rev1,
MDCG 2022-9, …

MDCG Guidelines



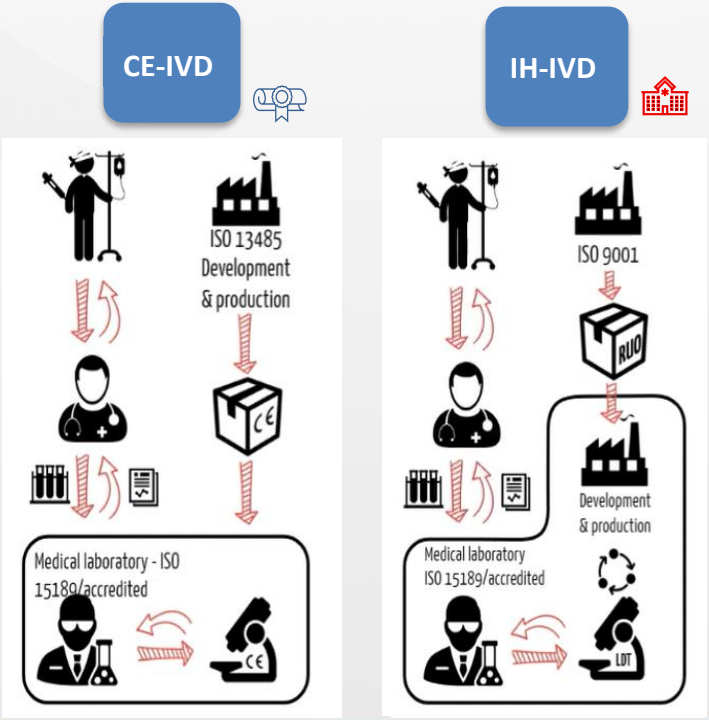


IVD's under the IVDR

Main goal:
Regulating medical devices' quality, safety and reliability

Impact:

- More demanding requirements for manufacturers and health institutions
- Use of IH-IVDs will be restricted
- Discouraging innovation for diagnostics



Conformity assessment is needed before use of the device

IH-IVD article 5.5

Competent authority

Justification of use of IH-IVD

Quality Management System

General Safety Performance Requirements

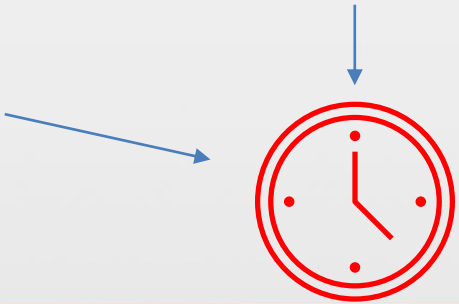
- Risk management
- Performance evaluation studies
  - Scientific validity
  - Analytical validity
  - Clinical validity
- Post market surveillance studies

CE-IVD

Notified Body

175 pages

- *10 chapters, 123 articles*
- *XVII Annexes*



Request for an incubation period for new technologies in rare diseases

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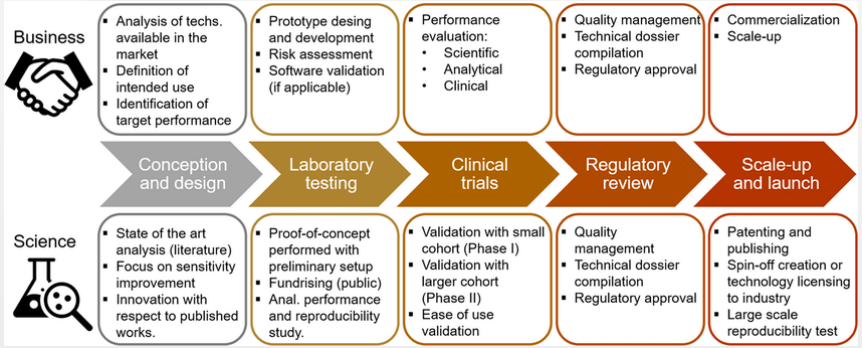
if no incubation time

discourage investment in technological and medical innovations

- jeopardize patient health
- reverse all the initiatives of Europe to reduce the diagnosis time

European Commission



Development process of a diagnostic device

G Rosati et al, ACS Nano 2021, 15, 11, 17137–17149

Proposal "*NEW*" MDCG guideline / paragraph

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Importance: Keep harmonization in EU and protecting the aim of the IVDR

Article 54: Derogation from the conformity assessment procedures possible

54.1: …level of member state to bring a product on the market (limited time period)

54.2-4: … possibility to made derogation European wide for the device

Article 54 of the IVDR provides that the national authorities may authorise the use of a specific device even though the conformity assessment procedures have not been carried out if the use of the device in question is in the interest of public health or patient safety or health. The European Commission has the possibility of extending national derogations to the entire territory of the Union.

Proposal "*NEW*" MDCG guideline / paragraph

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Importance: Keep harmonization in EU and protecting the aim of the IVDR

"*NEW* " MDCG guideline explain the conditions before derogation can be given in case of a new innovation for rare disease.

- the minimum level of IVDR conformity what is needed
- A minimum level of patient safety in the first period of using the test should be warranted.
- The conditions explained in the MDCG document shall guide the laboratory/organization which recalls this derogation

MDCG 2022-14

MDCG Position Paper **Transition to the MDR and IVDR** Notified body capacity and **availability of medical devices and IVDs**

August 2022

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18. The MDCG acknowledges the specific situation of **'orphan devices'** and will pursue work with a view to providing a definition for 'orphan devices' and ***suggesting specific guidance or other means of assistance for those products*** to be able to meet the legal requirements. Sustainable solutions are also needed in the mid- and long-term for orphan devices. [actors: MDCG TF on orphan devices]

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Task Force of IVDR of ESHG is willing to support