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جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی
Ministry of Health and Medical Education
IR.IRAN

اداره کل تجهیزات پزشکی
National Medical Device Directorate

Key changes of regulation (EU) 2017/746 on In Vitro Diagnostics Devices

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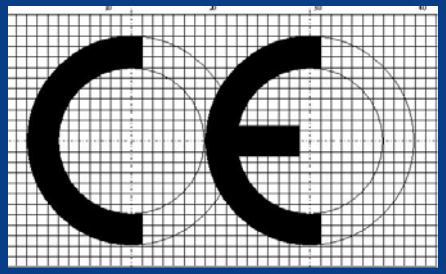
IVD department



What is CE?

CE Marking is the symbol of conformity with the EU Directives, which shows that the product on which it has been affixed is healthy and safe for the purposes of people, domestic animals and environment.

In vitro diagnostic medical devices (IVDs) are subject to the European Directive 98/79/EC (IVDD) 27 October 1998

A subgroup of medical products, their market access, use, and market surveillance is regulated.

In-Vitro Diagnostic Directive 98/79/EC

In-Vitro Diagnostic Regulation 2017/746

What is the difference between a Directive and a Regulation?

- **EU Directive:**

- Applicable to all Member States
- Sets certain aims, requirements and concrete results that must be achieved in every Member State
- National authorities must create or adapt their legislation to meet these aims by the date specified in each given Directive

- **EU Regulation:**

- Immediately applicable and enforceable by law in all Member States
- As good practice, Member States issue national legislation that defines the competent national authorities, inspection and sanctions on the subject matter.

IVD Regulation
What you need to know

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Transition period

‘Transition period’

5 years after entry into force for IVDR

Full application for the IVD Regulation: **26 May 2022**

changes

- **Product scope expansion**
- **Reclassifiation of devices according to risk**

- **More rigorous clinical evidence requirements**
- **More stringent documentation**
- **Identifiation of “person responsible for regulatory compliance**

- **Implementation of unique device identification**

- **More rigorous surveillance by Notified Bodies**
- **Greater Scrutiny of Notified Bodies**

Key changes

Risk classes

- Move from list-based approach to risk-based approach
- Four risk categories: A (low risk) to D (high risk)
- New NBOG codes for NB designation

Conformity Assessment Routes

- Amended to reflect the new classification rules
- Introduction of sampling for Bs & Cs
- More manufacturers need to use a Notified Body

Performance evaluation

- Process of performance evaluation defined
- Required throughout the lifetime of the device
- Plan for performance evaluation
- Provision for interventional performance studies

Key changes

Clinical evidence	• New requirement to provide a body of clinical evidence; required reports • Scientific validity, analytical performance, and clinical performance
Post-market	• Post market performance follow-up (PMPF) new requirement • Requirement for PMS plan and PMS • Incident reporting and trending
Scrutiny & traceability	• New requirements in technical documentation will mean audit and updates to all technical files • Summary of Safety and Performance for Class C & D • Unique Device Identifier (UDI)

Scope

Scope – Definitions that apply
In Vitro Diagnostic MD

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system

Whether used alone or in combination, intended…to be used in vitro for the examination of specimens, including blood and tissue donations… from the human body

Solely or principally for…providing information

concerning a physiological or pathological **process or** state

concerning congenital **physical or mental impairments**

concerning the predisposition to a medical condition or a disease

to determine the safety and compatibility with potential recipients

to predict treatment response or reactions;

to define or monitor therapeutic measures.

What is NOT an IVD…

(a) Products for **general laboratory use** or **research-use only products**, unless such products, in view of their characteristics are specifically intended by their manufacturer , to be used for in vitro diagnostic examination

(b) **invasive sampling devices** or those which are **directly applied to the human body for the purpose of obtaining a specimen**

(c) internationally certified reference materials

(d) materials used for external quality assessment schemes.

Classification

New classification of IVDs by risk

Risk classes A, B, C & D (where D is the highest) – Annex VIII.

- Borderline issues will be referred to the CA of the manufacturer or Authorised Rep; if this is different to the CA of the NB, they will consult.

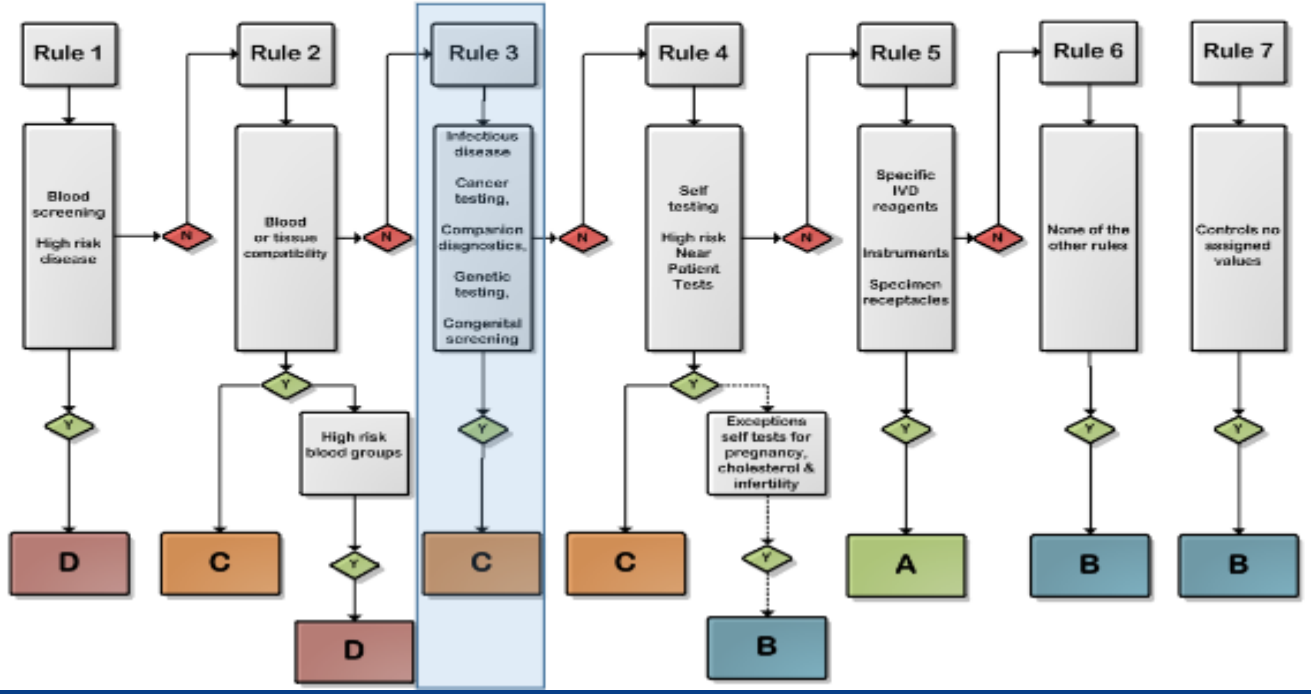
- IVD Classification Rules based on GHTF/IMDRF Rules (JP, Aus, Can); IVD's will fall in to 1 of four classes; A to D with A being the lowest risk

- If there is more than one potential application for a test, and the intended use is of the lower classification, there must be a specific exclusion in the labelling.

- Where more than one rule applies, the highest classification will be used.

The New EU IVDR:

Annex VIII - Classification Rules:



New classes of IVD devices

Class D

High public health risk, high personal risk

Examples
- HIV 1/2,
- Hepatitis C virus
- Hepatitis B virus
- HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems
- CHAGAS
- Syphilis (used to screen blood donations)

Class C

High personal risk, moderate to low public health risk

- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests

Class B

Moderate to low personal risk, low public health risk

- Thyroid function
- Clinical chemistry

- Self-test devices listed as *not* Class C -> Pregnancy, Fertility, Cholesterol tests; and detection of glucose, erthrocytes, leucocytes and bacteria in urine

Class A

Low personal risk, low public health risk

- Accessories
- Wash buffers
- Specimen receptacles
- Instruments
- Culture media

'Near patient tests' are classified in their own right

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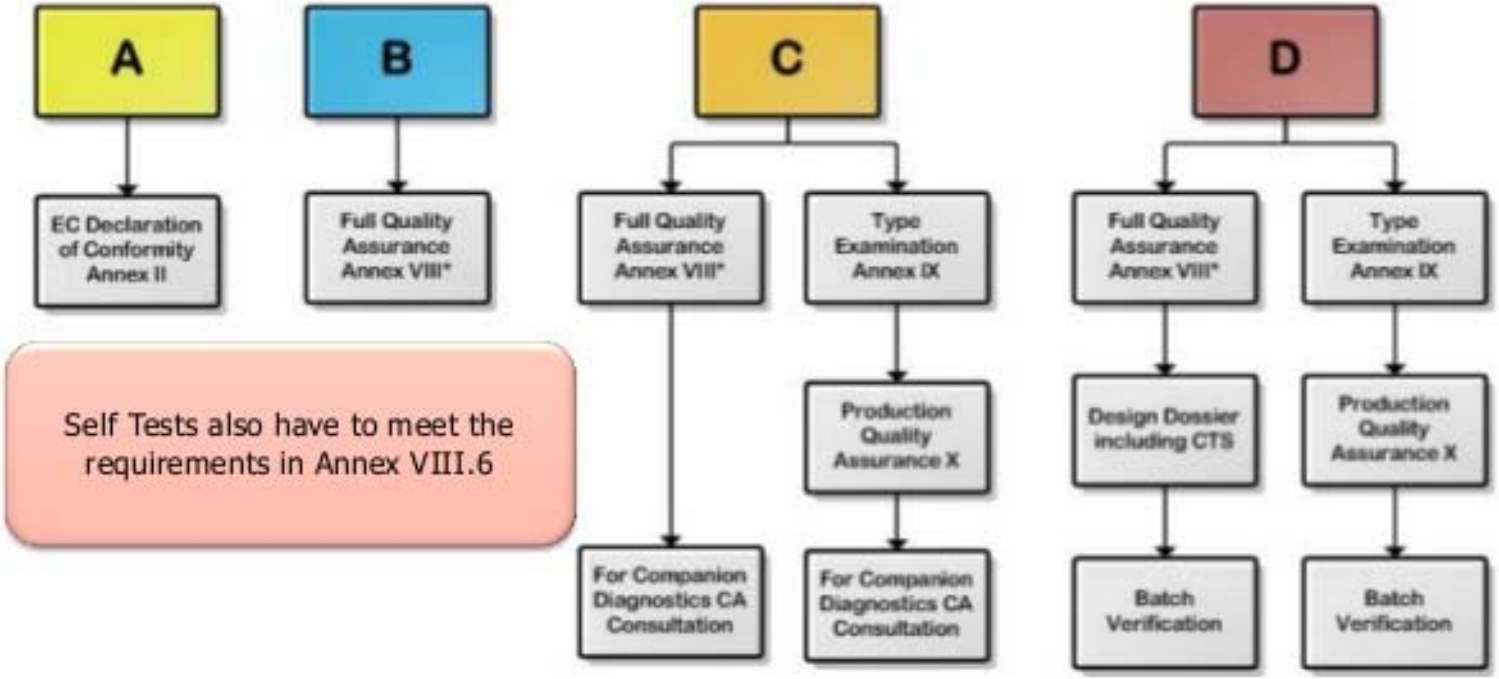
Conformity assessment

Conformity Assessment Routes



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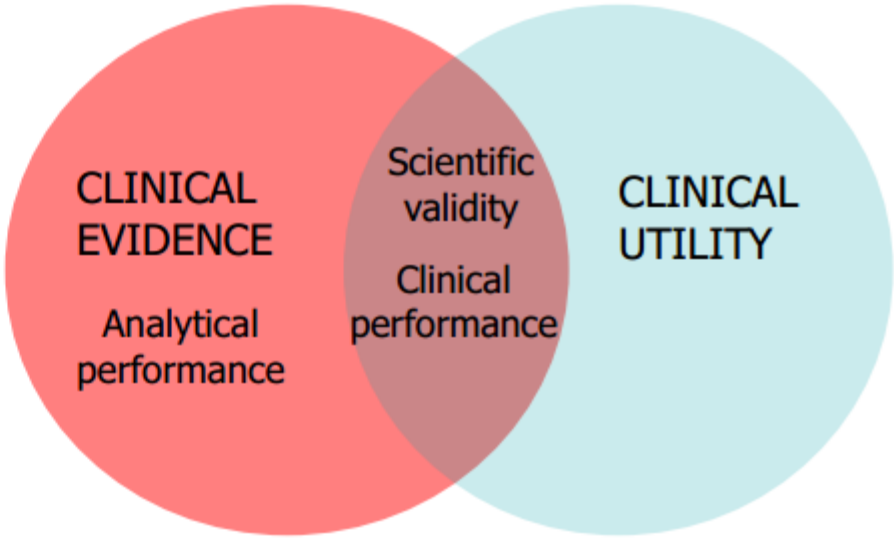
Clinical Evidence and Performance Evaluation

Clinical Evidence

New requirement for Clinical Evidence

Clinical evidence *= clinical data and performance evaluation results, pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit and safety, when used as intended by the manufacturer*



Performance Evaluation

Process of obtaining clinical evidence = Performance Evaluation

- Done according to a **Performance Evaluation Plan**
- Collated as a **Performance Evaluation Report**
- Continuous during life-time of the device

Placing a device on the market

1. Pass a conformity assessment

This does not apply to most Class I medical devices and Class A in vitro diagnostic devices

2.Draw up a declaration of conformity (Annex IV of the MDR and IVDR)

3.Place a CE mark on the device

CE marks are not unique to medical devices

4. Assign a Basic UDI-DI and provide it to the UDI database

For devices other than custom-made devices

5.Submit key information about the manufacturer, and authorised representative and importer if applicable, to the electronic system (Eudamed)

For devices other than custom-made devices

6.Place your CE marked device anywhere in Europe or put your device into service

Thank you for your attention