

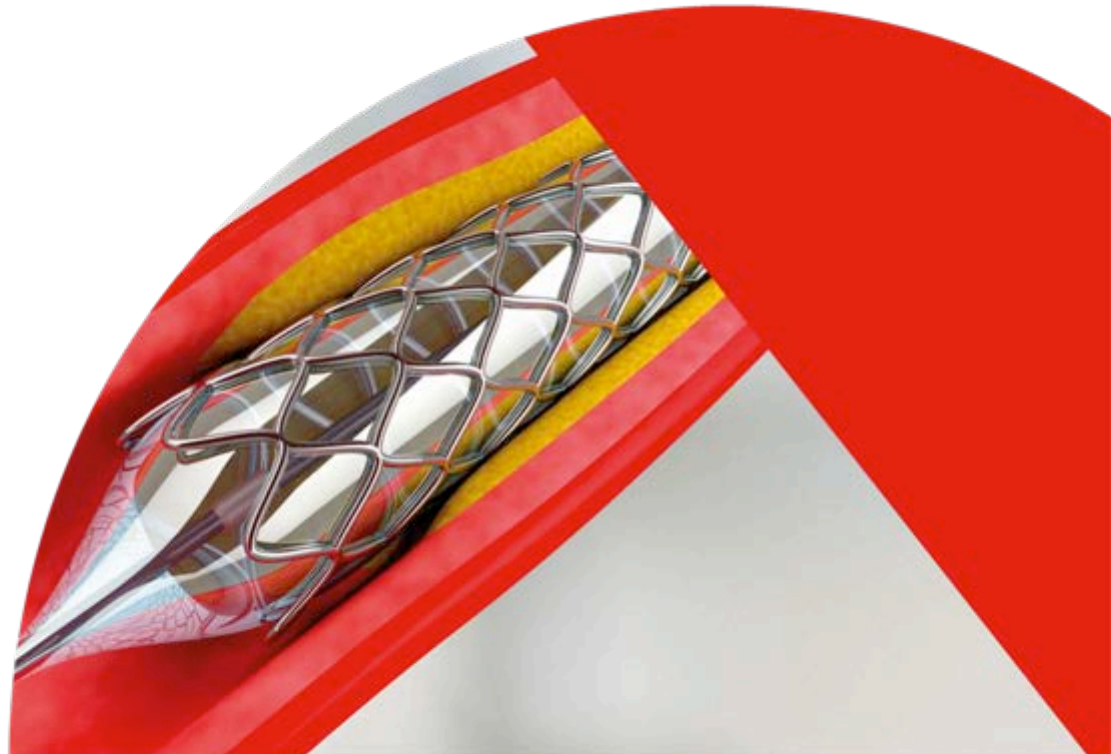


IVD Regulation

What you need to know

Erica Conway

5th May 2017



First Question: 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
- Sets a process for it to be implemented by Member States
- National authorities **must create or adapt their legislation to meet these aims** by the date specified in each given Directive

EU Directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so. **Regulations** are the most direct form of EU law - as soon as they are passed, they have binding legal force throughout every Member State, on a par with national laws. National governments do not take action themselves to implement EU regulations, but do ensure their national law does not define the subject matter any further.

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- **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.

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What exactly is changing?

- Medical Devices Directive **AND** Active Implantable Directives



- Medical Devices Regulation

- In-Vitro Diagnostic Directive

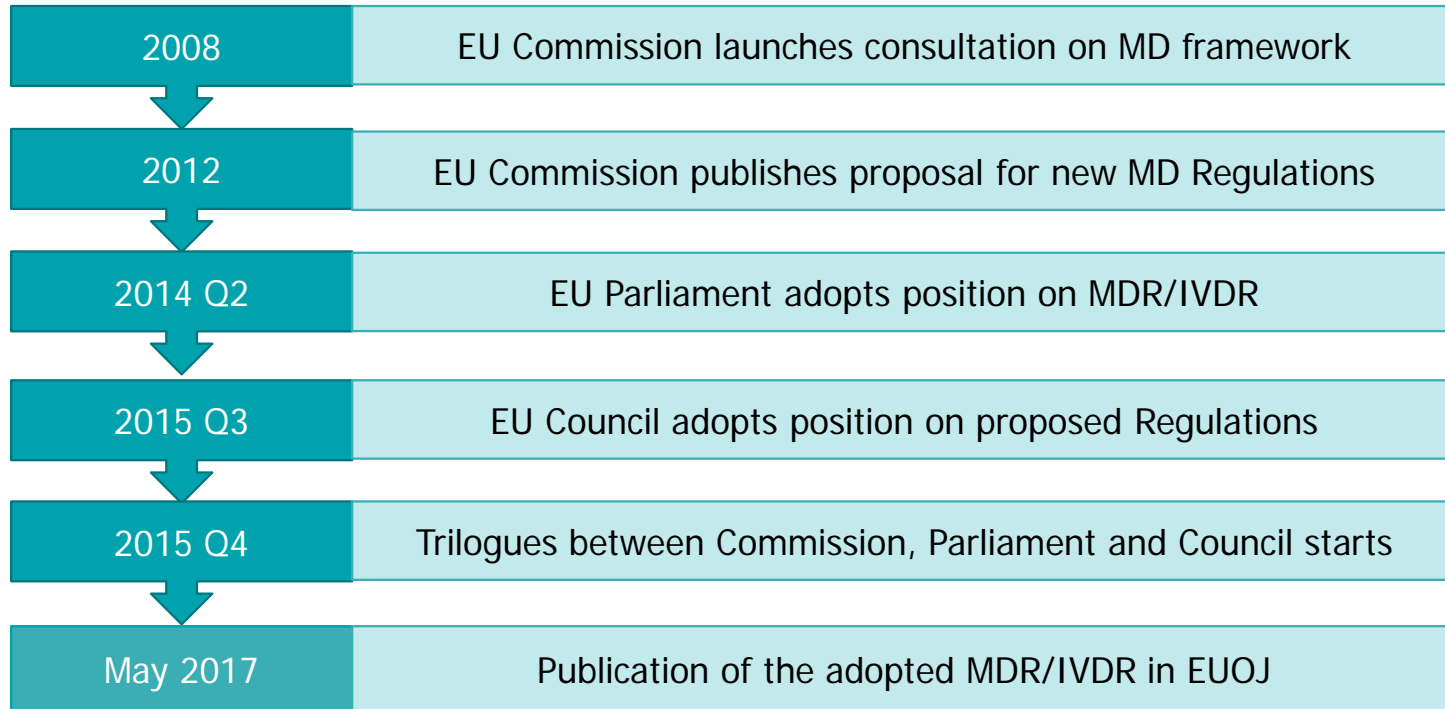


- In-Vitro Diagnostic Regulation



MDR/IVDR status update

The EU's new Medical Devices Regulations



Latest progress

*On 25 May 2016 during the last Trilogue, **political agreement was reached** on new MD and IVD Regulations nearly 8 years after initial negotiations kicked off...*

7 Mar 2017: Final adoption by the Council

21 Mar 2017: Discussion and vote in ENVI committee

4-5 Apr 2017: EP 2nd reading (Final adoption by European Parliament)

5 May 2017: Publication in Official Journal of the European Union (EUOJ)

➤ EU 2017/745 for MDR;

➤ EU 2017/746 for IVDR

A little clarity

The meanings of some words

- Entry into force

Publication of the new Regulation in EU Official Journal + 20 Days

- Texts take effect: **25 May 2017**

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- Date of application (DoA)

'Transition period'

3 years after entry into force for MDR

5 years after entry into force for IVDR

- Full application for Medical Devices Regulation: **26 May 2020**
- Full application for the IVD Regulation: **26 May 2022**

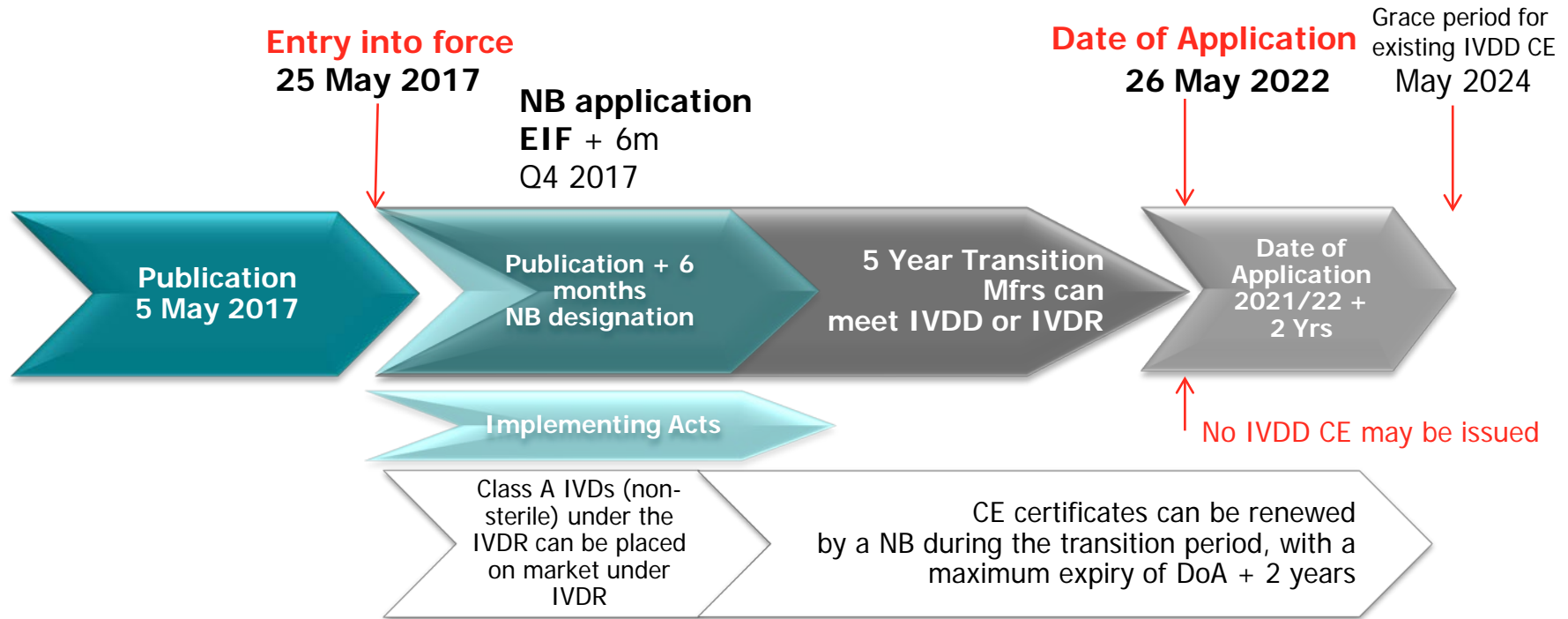
IVDR update

Medical devices: deal reached on new EU rules

Alignment of the MDR and IVDR

- ‘...There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices,
- whereas the **horizontal aspects common to both sectors should be aligned.**’

Transitional arrangements for IVDR



Implementing and Delegated Acts

- Many instances of Delegated Acts and Implementing Acts necessary to make IVDR “operational”
- Unclear when these will be available...



e.g:

- Regulatory status of groups of products
- Common Specifications
- Format of Summary of Safety and Performance (SSP)
- UDI
- EUDAMED
- List of NBOG codes
- NB designation procedure

...

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

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Conformity Assessment Routes



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

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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

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Post-market



- Post market performance follow-up (PMPF) new requirement
- Requirement for PMS plan and PMS
- Incident reporting and trending

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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

Medical Device

- 'medical device' means 'medical device' as defined in Regulation (EU) No [Reference to the future Regulation on medical devices].

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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..

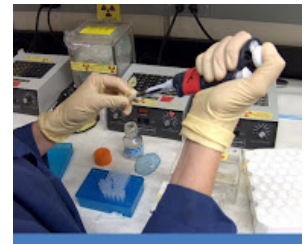
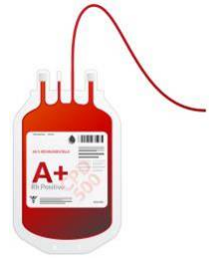
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In Vitro Diagnostic MD

- 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.

Consideration of scope...

Placing on the market

- 'placing on the market' means the first **making available** of a device, other than a device for performance study, **on the Union market**;

- 'making available on the market' means any **supply** of a device, other than a device for performance study, for **distribution, consumption or use** on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

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- Includes devices offered by **'information society services'**
- A kit does not have to be sold in EU; the IVDR applies if it has been **used to test EU citizens**
- Enforcement by competent authorities
- If a Member State has grounds for concern based on the protection of public health, the provider will be required to cease its activity.



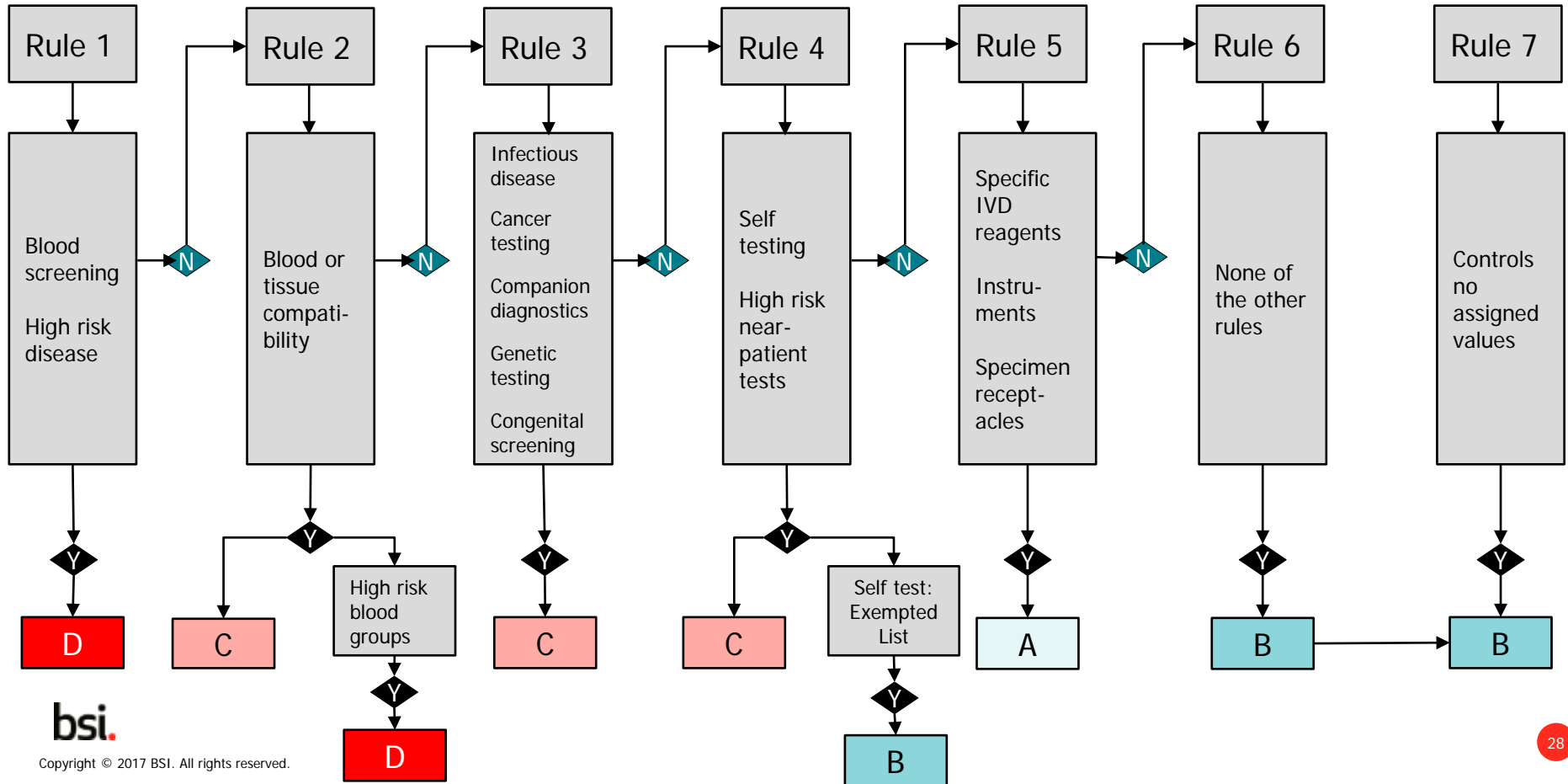
Classification

New classification of IVDs by risk



- Risk classes A, B, C & D (where D is the highest) – Annex VIII.
- Implementing Acts and guidance.
- 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.
- Role of Medical Device Coordination Group (MDCG).
- 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.

Classification



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)

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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
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Class B

**Moderate to low personal risk,
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- Thyroid function
- Clinical chemistry
- Self-test devices listed as *not* Class C -> Pregnancy, Fertility, Cholesterol tests; and detection of glucose, erythrocytes, leucocytes and bacteria in urine

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Class A

**Low personal risk, low
public health risk**

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

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Newly defined devices

Companion Diagnostic

means a device which is essential for the safe and effective use of a corresponding medicinal product to:

- identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
- identify, before and/or during treatment, patients likely to be at increased risk for serious adverse reactions as a result of treatment with the corresponding medicinal product;

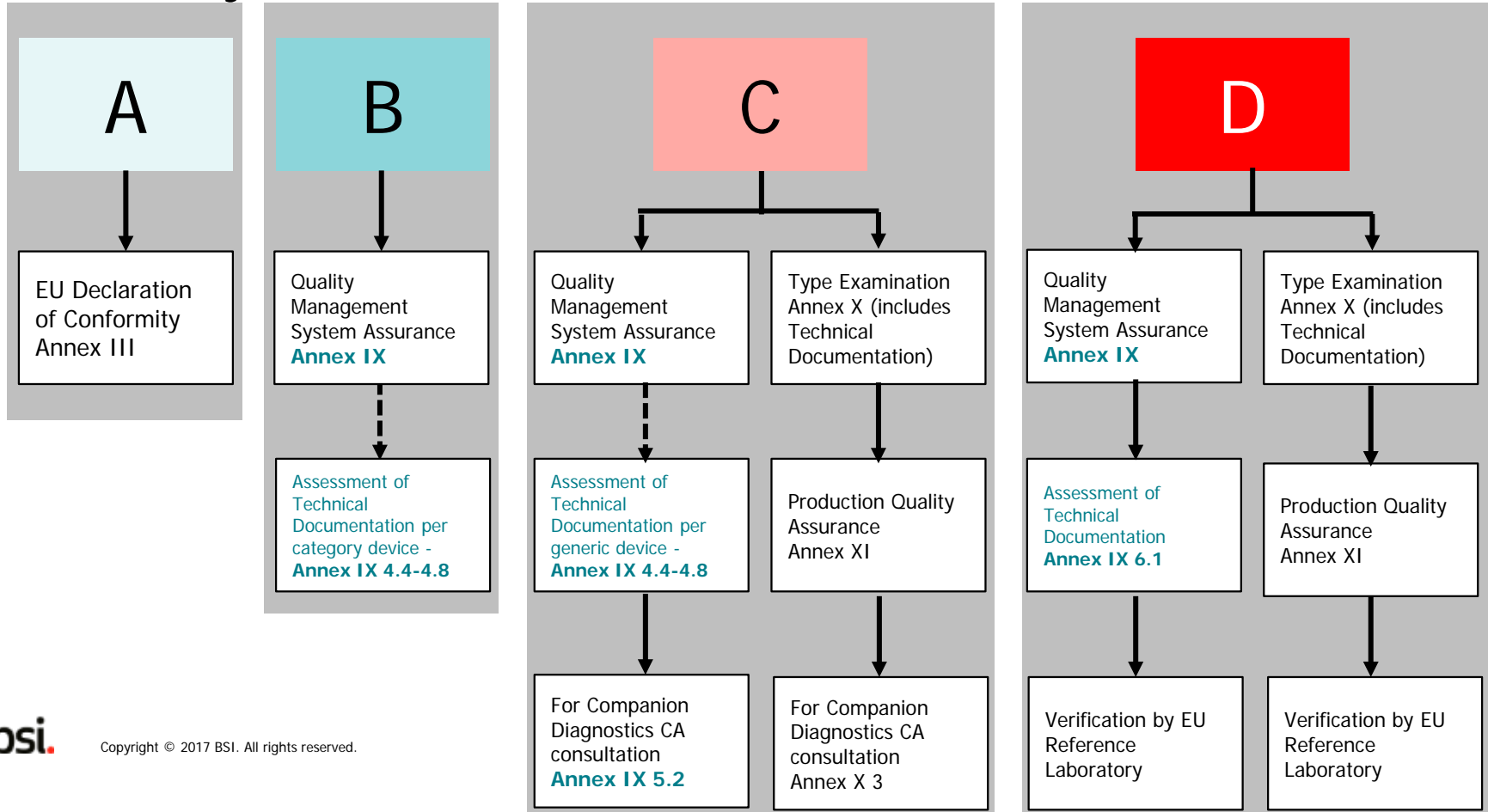
device for 'near-patient testing'

means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional



Conformity
assessment

Conformity assessment



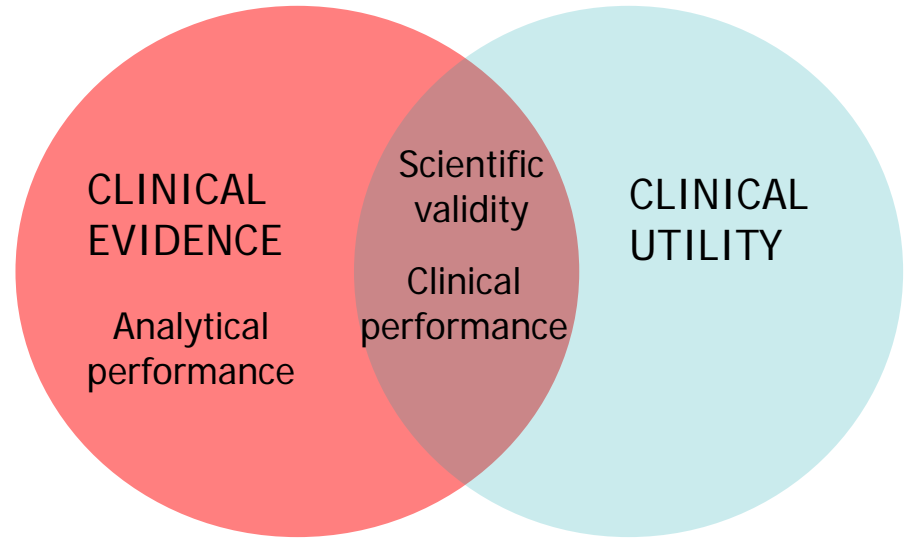


Clinical Evidence and
Performance Evaluation

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



Where can I find full details of the changes?

bsigroup.com/MDR-revision

bsigroup.com/IVDR-revision

Webinars: bsigroup.com/webinars

Whitepapers: bsigroup.com/whitepapers

Please ask if you want any extra information from BSI.

