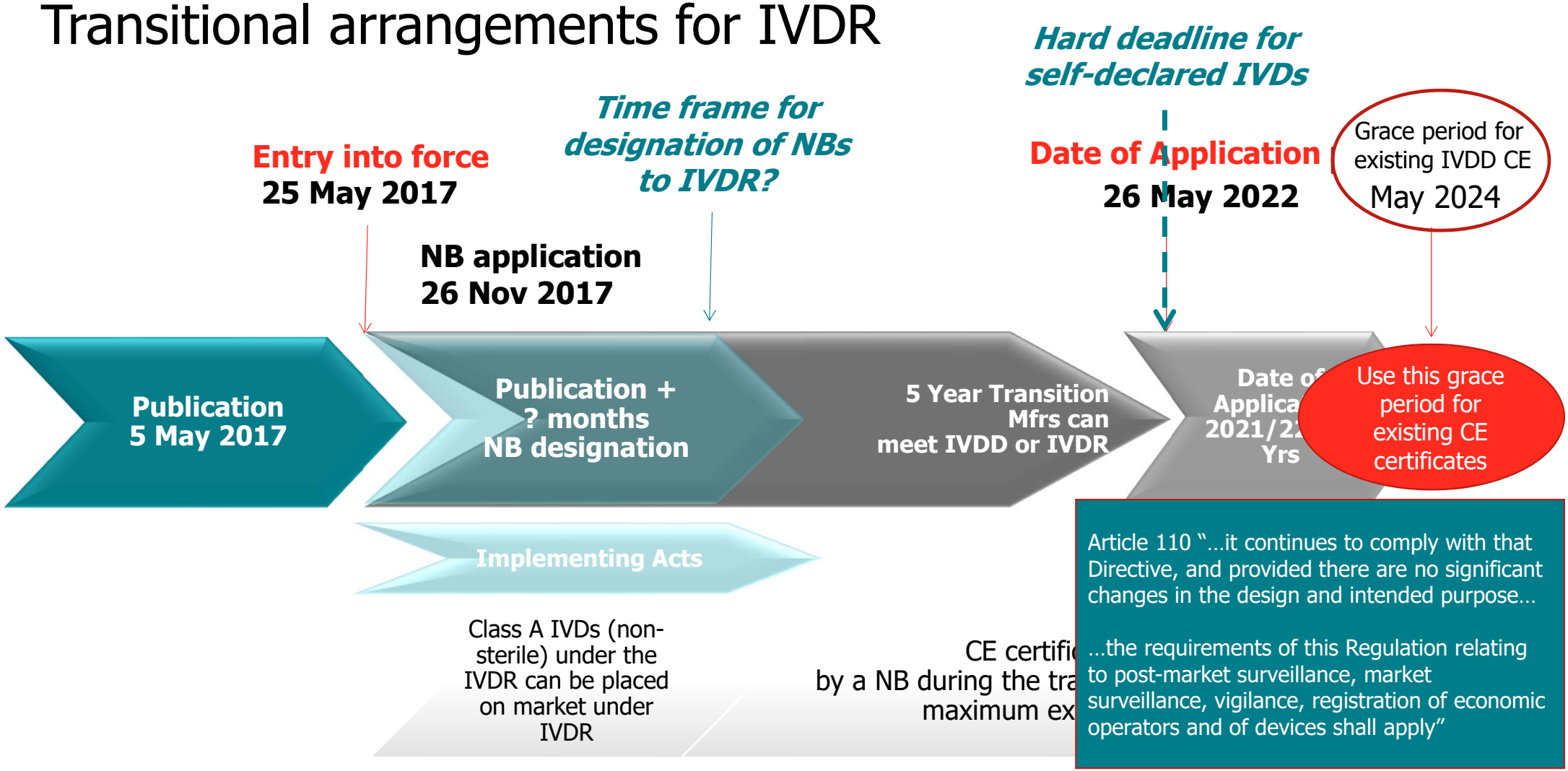
Webinar: IVDR Readiness

Dr Erica Conway
Global Head – IVD Medical Devices

29 May 2019

By Royal Charter

Transitional arrangements for IVDR



Intent

- IVDR Readiness resource
- Highlights main changes to the IVDR
  - Tool for Manufacturers
- Other resources and information to assist during IVDR transition

✓ View to the 26 May 2022 deadline (for most IVDs)

bsigroup.com/IVDR-revision

BSI Transitions
In Vitro Diagnostics Regulation

Click here to download!

IVDR Readiness Review


BSI Transitions
In Vitro Diagnostic Regulation

In-Vitro Diagnostic Regulation (IVDR)
Readiness Review

Company Name
Address
Certification No.
Date:
Contact Name
Job Title
Telephone
Email

How ready are you for the IVD Regulation?

The IVD industry is undergoing significant change. The IVDR, which replaces the IVD Directive (98/79/EC), entered into force on May 25th 2017. This starts the transition period of five years for manufacturers selling IVD devices into Europe.

Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements. BSI is committed to ensuring a smooth transition for all clients wishing to certify to the IVDR.

This document allows you to detail how you intend to meet the additional requirements of the new Regulation, please use in conjunction with Regulation (EU) 2017/746. It is NOT an exhaustive checklist but contains summary statements of the significant changes.

Completion of this form is not mandatory and does not need to form part of the transition process, but can help with your internal preparation and be a useful tool for planning your transition strategy. Use the boxes below to list procedures, records and examples that address the additional requirements. This can be used as a gap analysis tool or as an aide memoire during your transition assessments.

Your BSI Team is here to support you on your journey, so please talk to us about your plans early on in your preparation. Further information can be found BSI IVDR revision page www.bsigroup.com/IVDRRevision.

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 have to take action themselves to implement EU regulations.

bsi. ...making excellence a habit.

Our interactive Readiness Review can be used to complete a gap analysis of your current documentation and systems against the requirements of the IVDR.

Detail how you intend to meet the new requirements, and list the documents and records that allow you to demonstrate conformity to the Regulation.

Scope & device classification

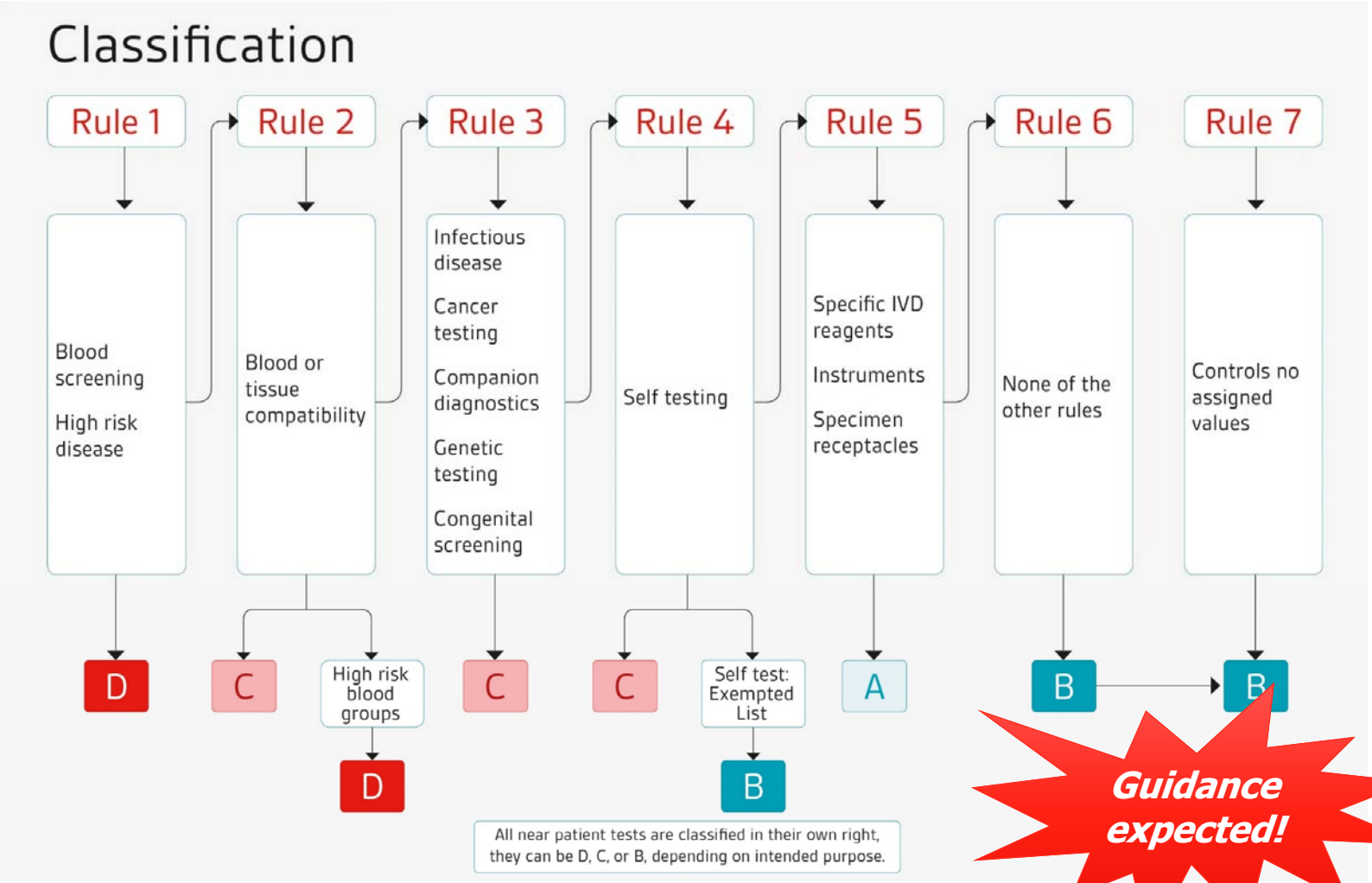
Gap Analyses on requirements

Your transition strategy

Keep the deadline in sight!

Scope & classification

bsi. ...making excellence a habit.



Guidance expected!

...Will mean 80-90% IVD devices will need a NB

1.1. Application of the classification rules shall be ***governed by the intended purpose, novelty, complexity and inherent risk*** of the devices.

Classification of IVDs

Work now on your classification!

Do not let borderline questions stop your transition progress

Review of technical documentation will be at the **same depth for all devices**, but there will be sampling proportionate to risk (i.e. B vs C)

More scrutiny on ***risk***, ***clinical evidence*** and ***post-market surveillance – for all classes!***

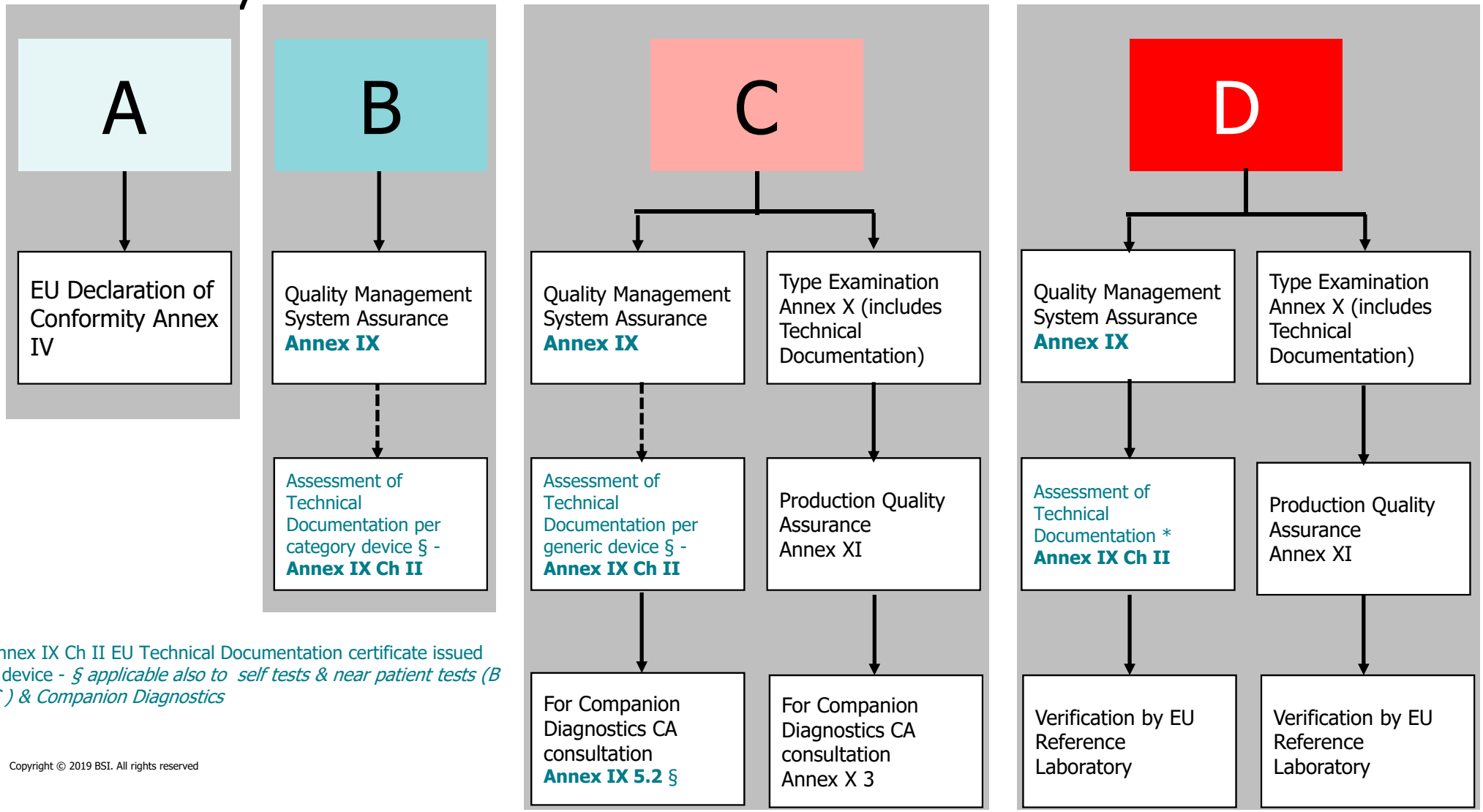
- **D** — High Population, High Patient risk
- **C** — Low Population, High Patient risk
- **B** — Medium-low patient
- **A** — Low patient risk

Conformity assessment

Your route to CE marking under the IVDR

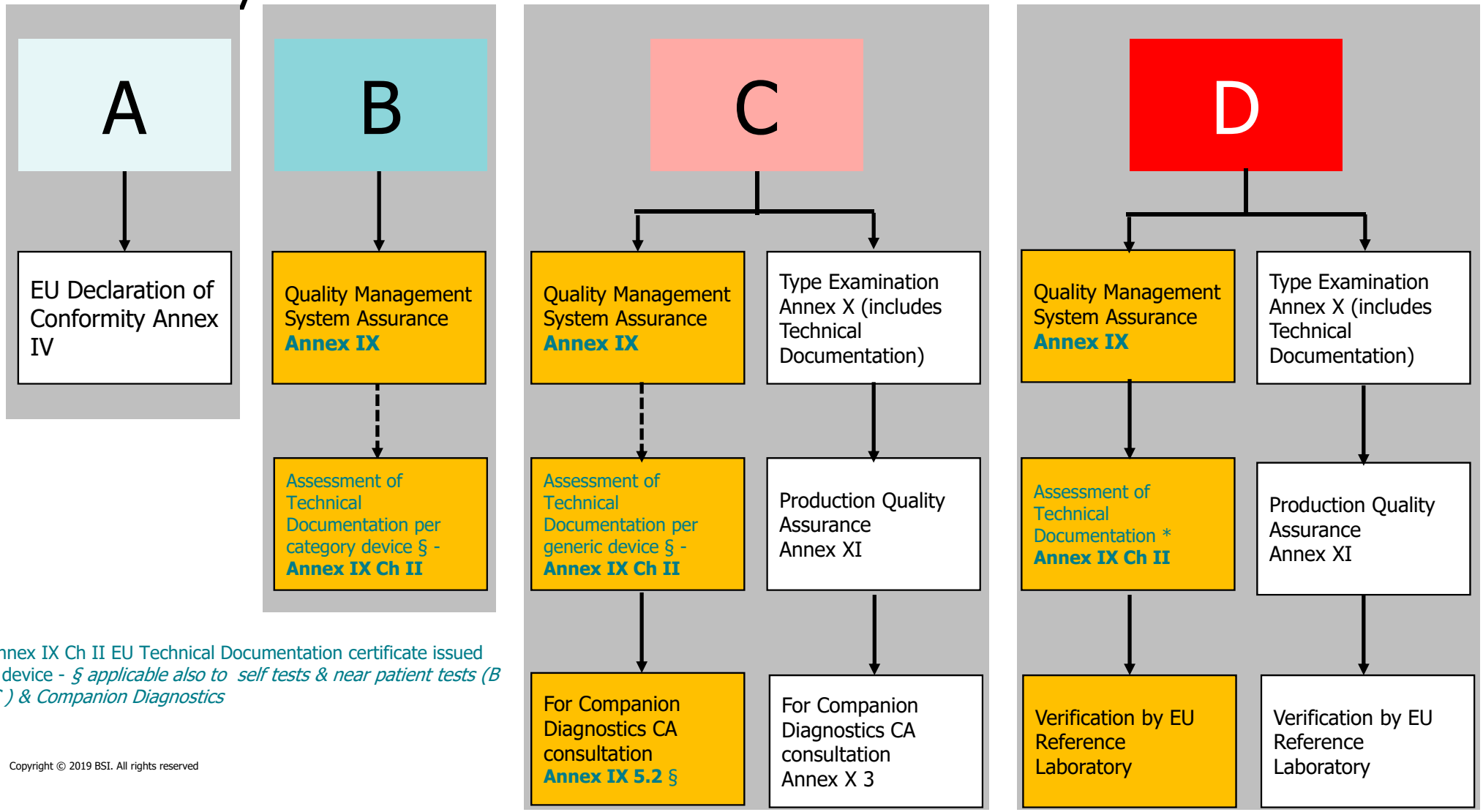
bsi. ...making excellence a habit.

Conformity assessment



* Annex IX Ch II EU Technical Documentation certificate issued per device - *§ applicable also to self tests & near patient tests (B & C) & Companion Diagnostics*

Conformity assessment



* Annex IX Ch II EU Technical Documentation certificate issued per device - *§ applicable also to self tests & near patient tests (B & C) & Companion Diagnostics*

Certificates issued under Annex IX

Class B & C devices

1. **EU Quality Management System certificate** (Annex IX, I & III)
    - Accompanied by assessment of technical documentation on representative basis for each generic device group (C) or device subcategory (B)
    - *Ref Article 48*

Certificates issued under Annex IX

Class B & C devices

1. EU Quality Management Syst certificate (Annex IX, I & III)
    - Accompanied by assessm technical documentation representative basis for e device group (C) or devic subcategory (B)
    - *Ref Article 48*

Class D & Others specified*

1. **EU Quality Management System certificate** (Annex IX, I & III)
2. **EU Technical Documentation Assessment certificate** (Annex IX, II exclu sec 5)
    - For each Class D device to be placed on the market
    - Reference laboratory will verify claimed performance and Common Specification requirements – *needs to be positive outcome*
    - MDCG consultation if no Common Specification
    - Verification of manufactured batches (Class D)

- ***OR*** **EU Technical Documentation Assessment certificate** (Annex IX, II sec 5)
    - For each device* to be placed on the market *(to be confirmed)*
    - Drug consultation for Companion Diagnostics

*Self-test and near patient tests, Classed B-D; Companion Diagnostics

Certificates and scopes

Requirements under Annex XII for Certificates

'Shall unambiguously describe the device or devices covered…

If Annex IX is your conformity route, then all devices will be covered by the scope of this certificate that have undergone conformity assessment

Class B & C devices *(not self test, NPT or CDx)* may be covered by this certification only

Quality Management System Assurance

- Identification of device or groups of devices
- Risk classification
- Intended purpose

Class B & C devices
(not self test, NPT or CoDx)

- Scope will cover the subcategory or generic group of devices
- Sampling plans for device groups

Certificates and scopes

Requirements under Annex XII

'Shall unambiguously describe the device or devices covered…

If you have a device that needs a product specific review (Annex IX, II), you will also be issued with a EU Technical Documentation certificate

Class D, or Class B & C devices that are self-test, near-patient tests (NPTs), or companion diagnostics (CDx)

Quality Management System Assurance

- Identification of device or groups of devices
- Risk classification
- Intended purpose

+

EU Technical Documentation

- a clear identification, inc. name, model and type, of the device/s
- intended purpose (IFU)
- risk classification
- Basic UDI-DI

QMS audit

- An on-site audit will be required to certify to IVDR requirements

- The audit scope must cover all devices/device groups that you wish to certify
  - Consider if you are doing your device portfolio 'in stages'

➢ **See resources** for QMS transition planning

Review of Technical Documentation

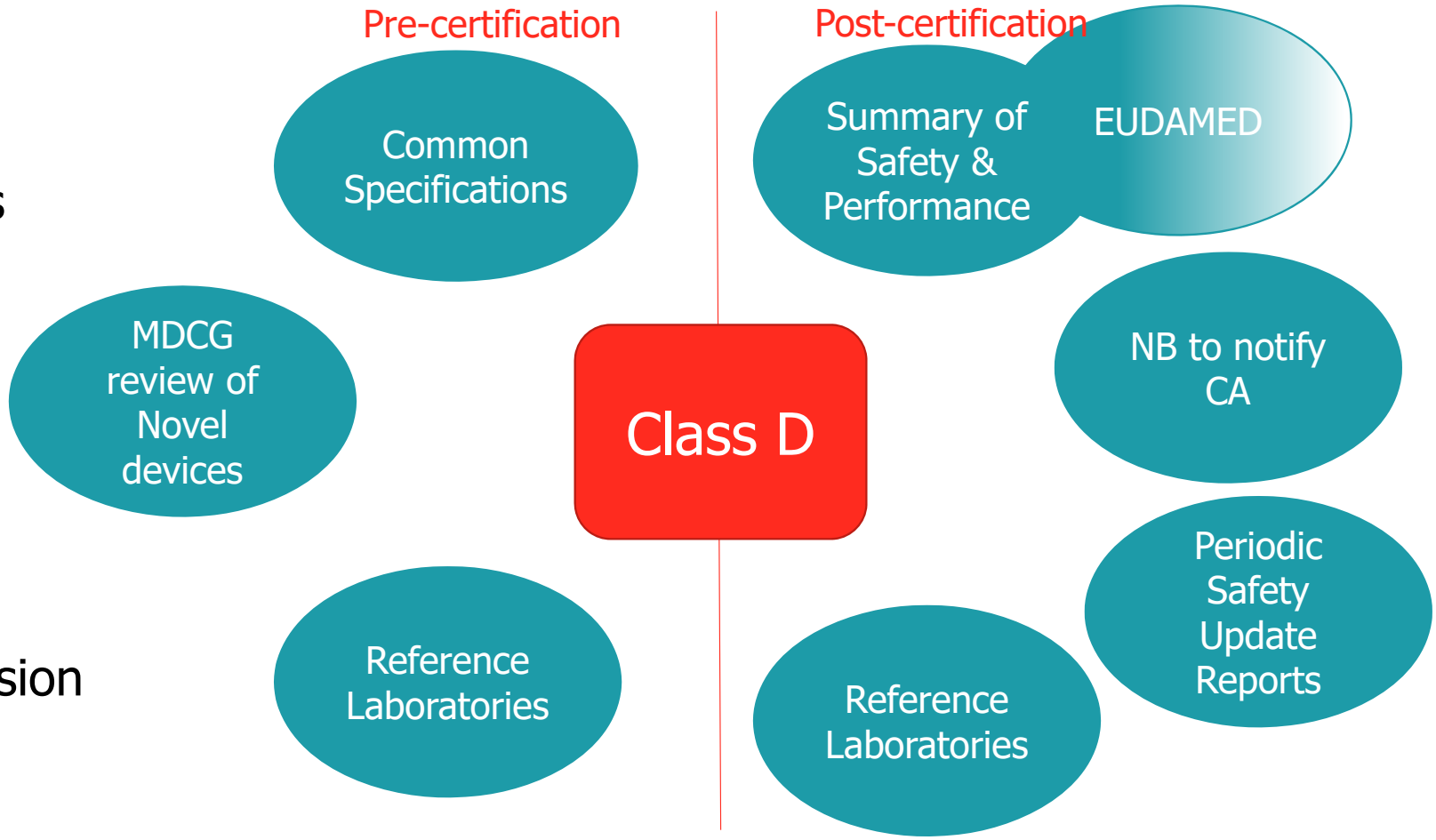
- Assessment of Technical Documentation will be needed for every device (Class D, self-test, near-patient test, or Companion Diagnostic device)
- Assessment of the Technical Documentation of *at least* one device of every group to be certified
  - Sub-category group (Class B)
  - Generic device group (Class C)
  - *Technical sampling:* Based on novelty of technology, risk of device and standard medical practice, similarities of design, technology and manufacturing
  - ➢ ***For device grouping**, suggestion:* use the IVDR (NBOG) codes (IVR, IVP, IVS if applicable); and use the intended use for Class Cs in addition
- Surveillance technical audits will be needed every year in the certificate cycle, where there are still devices to be reviewed

Scrutiny has increased

Scrutiny from…

- EU Reference Labs
- Competent Authorities
- Medical Device Co-ordination Group (MDCG)

➢ European Commission

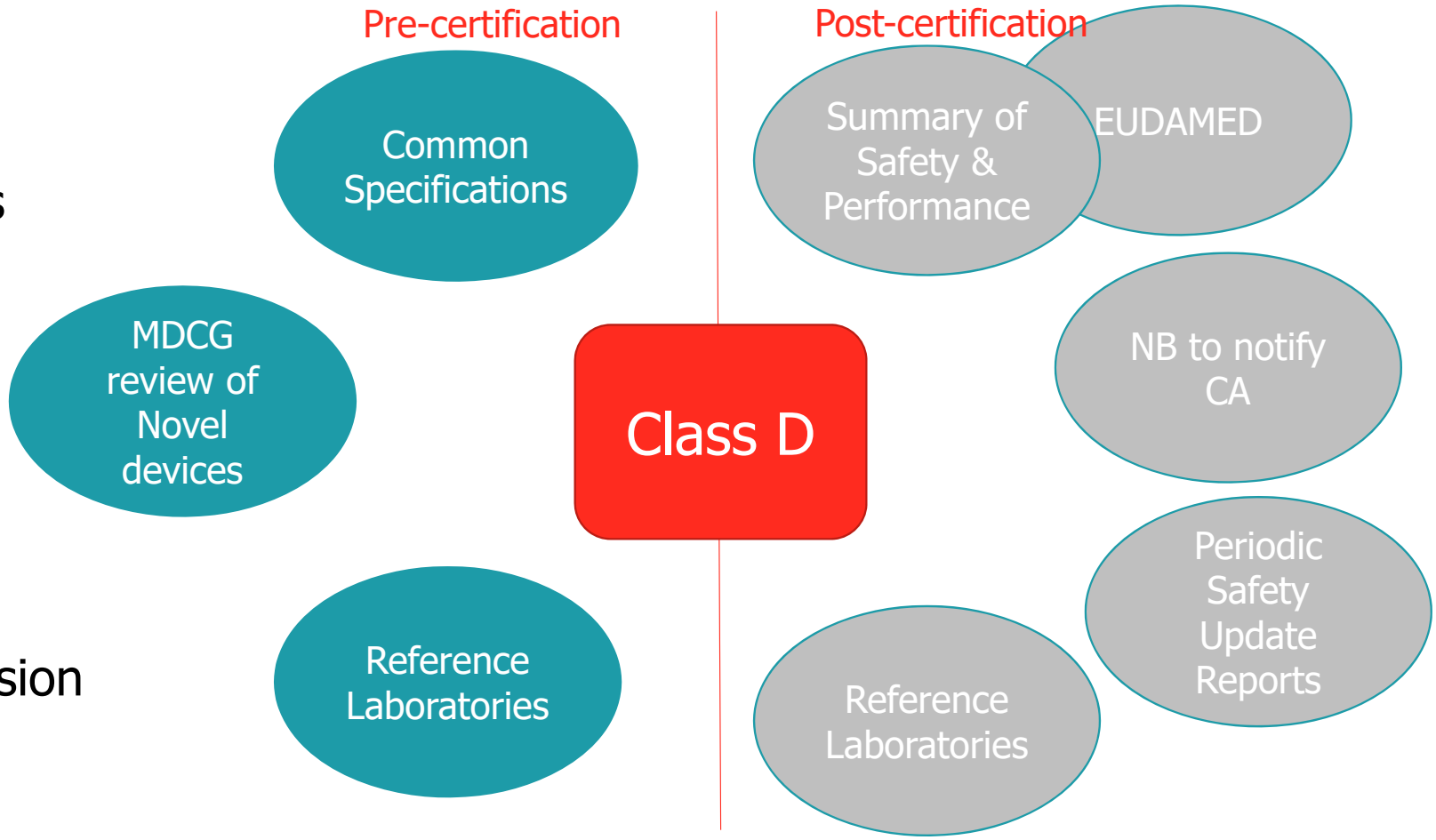


Scrutiny has increased

Scrutiny from…

- EU Reference Labs
- Competent Authorities
- Medical Device Co-ordination Group (MDCG)

➢ European Commission

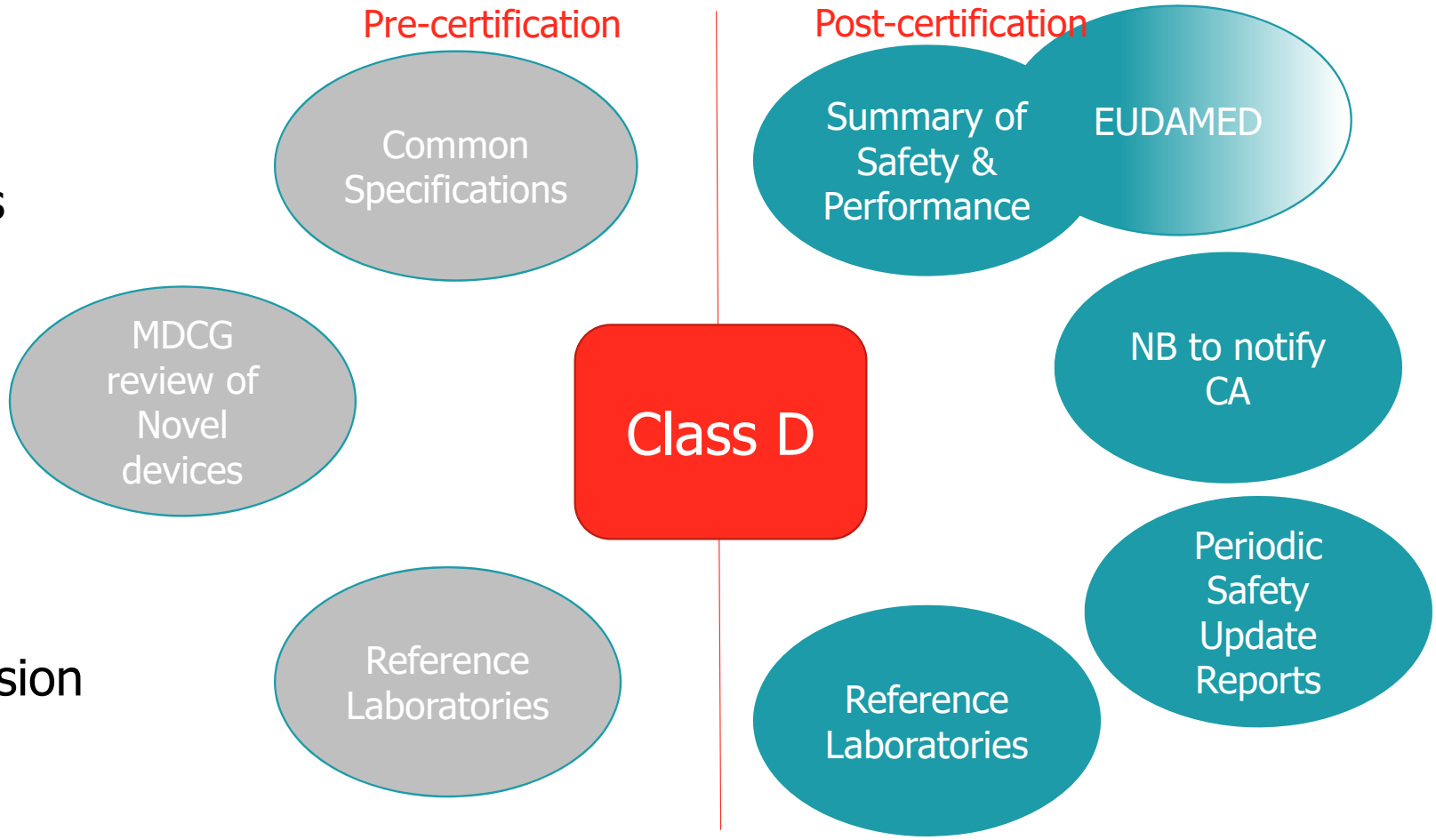


Scrutiny has increased

Scrutiny from…

- EU Reference Labs
- Competent Authorities
- Medical Device Co-ordination Group (MDCG)

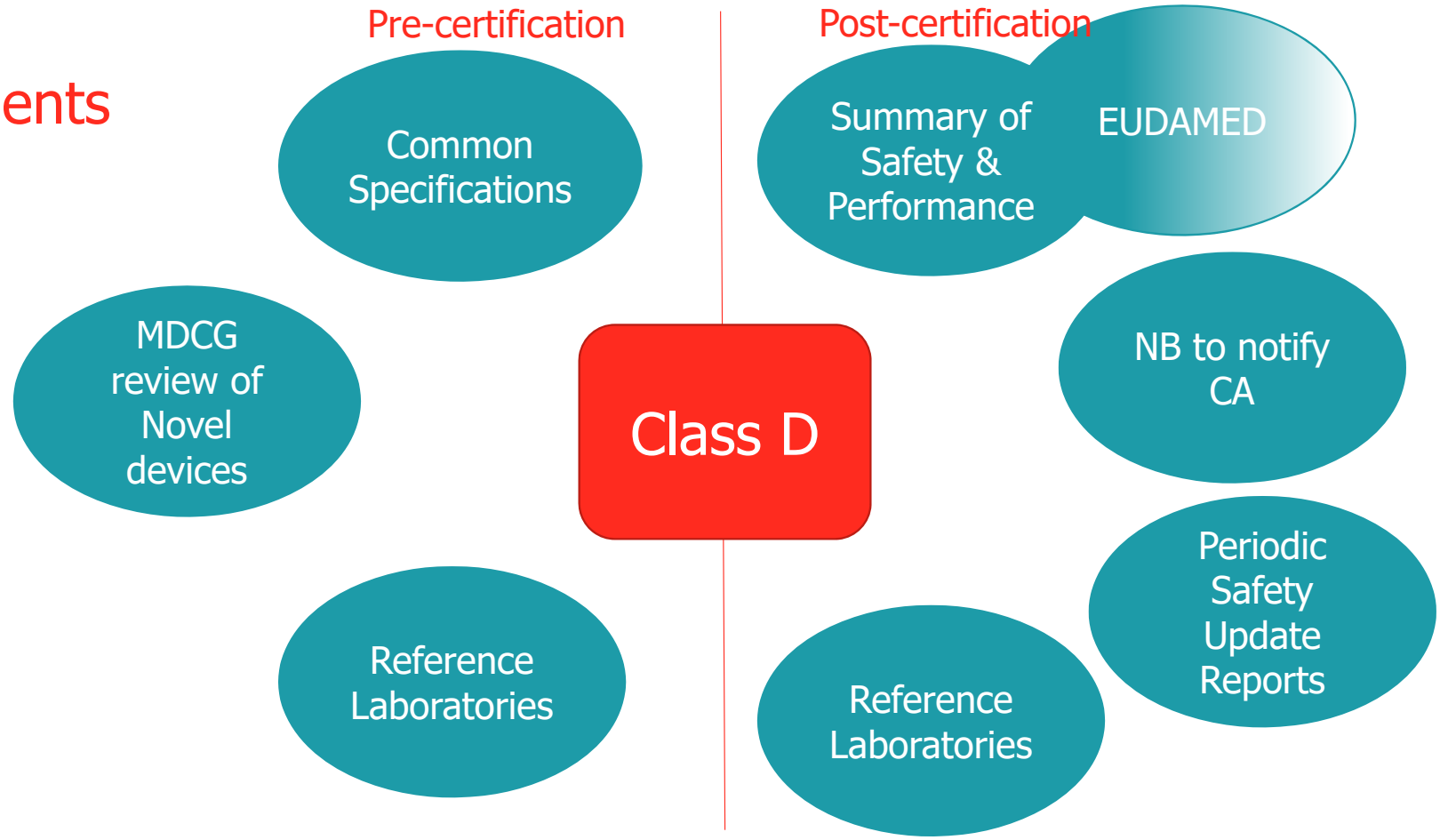
➢ European Commission



Scrutiny has increased

- Check requirements
- Prepare
- *Time lines may be affected*

- **Class C** devices will also need SSP & PSURs



Technical Documentation

bsi. ...making excellence a habit.

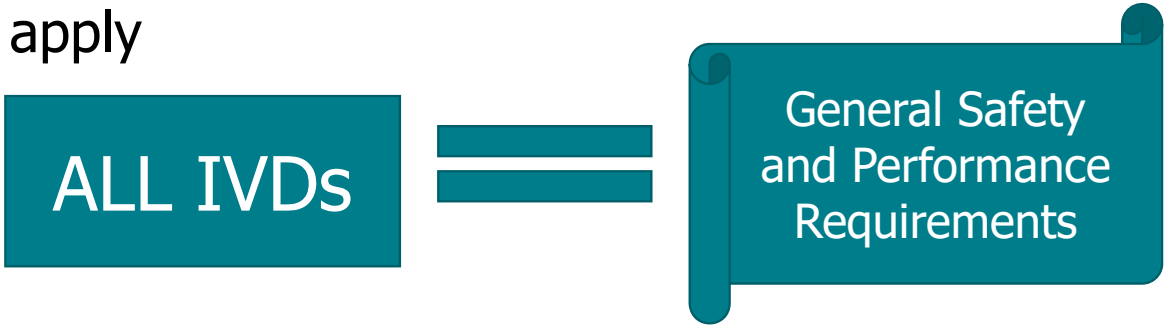
Technical documentation for all IVDs

- General Safety and Performance Requirements (GSPRs) are outlined under Annex I of IVDR

- **ALL IVDs** need to meet the requirements of the GSPRs
  - Devices that are within the scope of the IVDR
  - Including IVDs that have an EU In-house exemption

See BSI webinar!

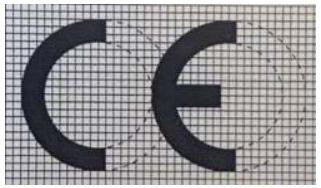
- For devices that are under performance evaluation, certain requirements of Annex I will still apply



IVDD Essential Requirements

→

IVDR General Safety & Performance Requirements



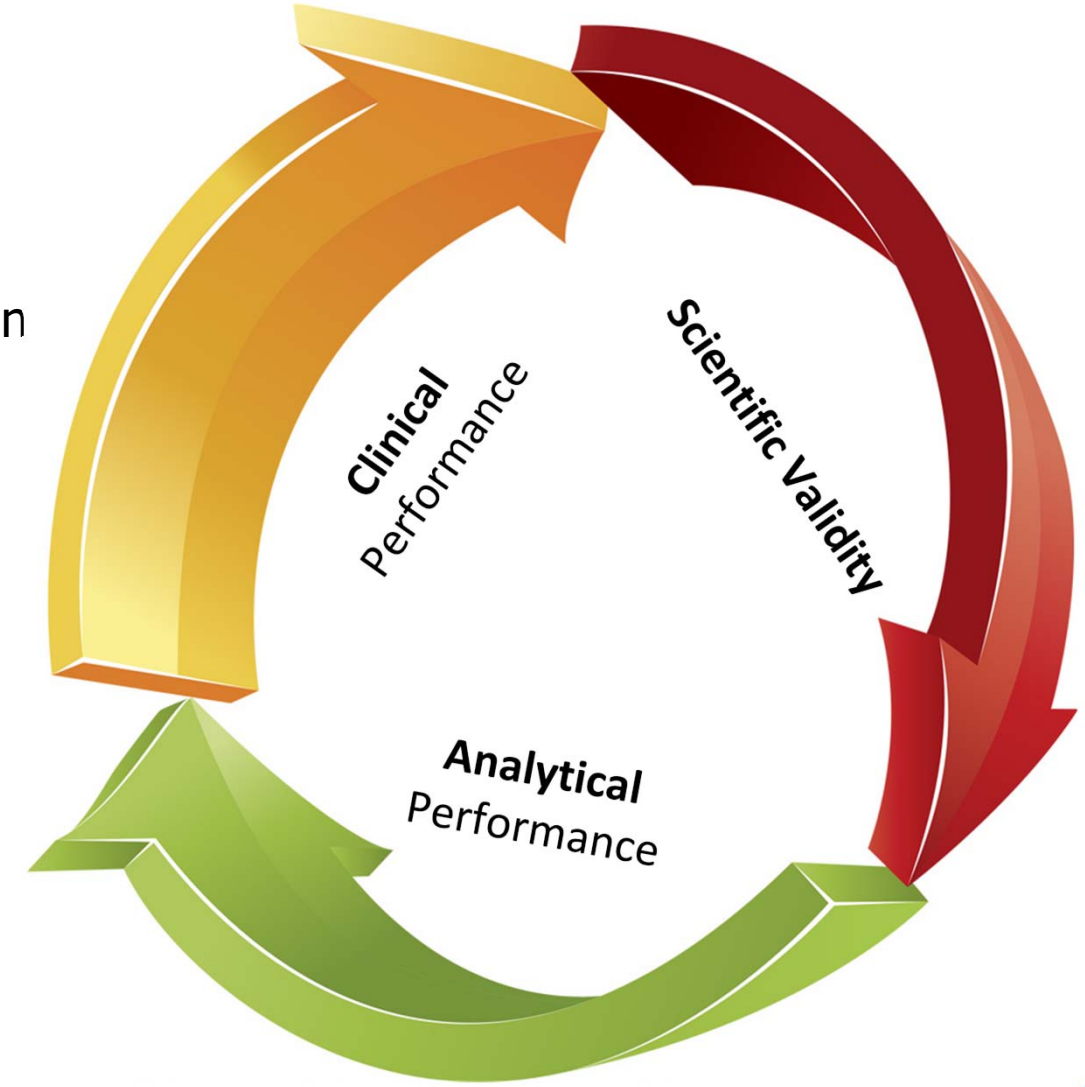
The General Safety and Peformance Requirements (Annex I) apply to all IVDs in order to conform and apply the CE mark under the IVDR.
- For devices under performance evaluation certain requirements will still be applicable
- Includes devices that are used in EU Institutions under exemption

Requirements are dependent on the device, therefore, audits will be needed of all existing devices to transition to the IVDR

New IVDs and existing CE-marked IVDs will need to comply with these requirements by 26 May 2022 (end of the transition period)

Performance Evaluation

- Sum total = **Clinical Evidence**
- ***Process*** of Performance Evaluation
- Done according to a **Performance Evaluation Plan**
- Collated as a **Performance Evaluation Report**
- Continuous during life-time of the device



Clinical Evidence

The Performance Evaluation will be a critical part of the technical documentation

…we will look for:

(reviewed against requirements under Annex II & XIII)

- **Performance Evaluation Plan**
- **Performance Evaluation Report**
  - Scientific Validity Report
  - Analytical Performance Report
  - Clinical Performance Report
  - & *Conclusion (see An XIII, 1.3.2)*
- **Post Market Performance Follow-up Plan**
  - Annex XIII part B
  - Linked to conclusion of PER
  - PMPF evaluation report shall update the PER
  - If deemed not appropriate, then justification to be given in the PER (An XIII, 8.)

Post-market obligations

- **Vigilance** requirements
  - Incident Reporting
  - Trending
- **Post-market Surveillance Plan & Post-market Surveillance**
  - Reviewed as part of Surveillance visits
  - Post-market surveillance Reports - Class A & B devices; or
  - Periodic Safety Update Reports (PSURs) - Class C & D devices
- **Post-market Performance Follow-up (PMPF)**
- For Class C & D devices, updates to the **Summary of Safety and Performance**, at least annually
  - An SSP will be needed at the time of CE application
  - Will be publicly available

‘Legacy’ devices

- *Not defined under the Regulations*
- There is no ‘grand-fathering’
- All parts of the IVDR apply
- General safety & performance requirements to be met:
- Annex I.1

*Devices shall **achieve the performance intended by their manufacturer** and shall be designed and manufactured in such a way that, **during normal conditions of use, they are suitable for their intended purpose**. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, **taking into account the generally acknowledged state of the art**.*

What we will look for…

- ✓ We will assess against all points under Annex I (GSPRs)
  - ❖ Note specific labelling requirements (chapter III)
  - ❖ Note specific information for the Instructions For Use (IFU, 20.4)
  - ➢ 20.4.1 The instructions for use *shall contain* all of the following particulars…
- ✓ We will assess against all points under Annex II (Technical documentation)
- ✓ We will assess against all points under Annex XIII (Performance Evaluation & Clinical Evidence)

Make it as easy as possible for your Assessor!

bsigroup.com/IVDR-revision

BSI Transitions
In Vitro Diagnostics Regulation

Download!

CE marking under the IVDR

Interacting with a Notified Body (NB)

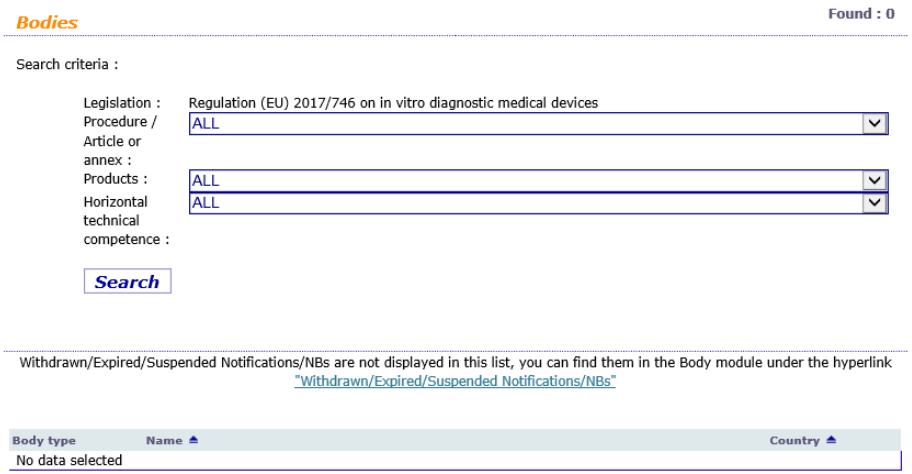
You have options!

- Manufacturer's choice for NB
- Important relationship
- http://ec.europa.eu/growth/tools-databases/nando/

- Check designation plans
  - Are they applying for your IVDR codes'
  - Designated NBs will be listed "Regulation (EU) 2017/746"

NB competence is defined by IVDR (NBOG) codes

- http://www.doks.nbog.eu/Doks/NBOG_F_2017_4_IVDR.docx; (EU) 2017-2185
- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en



What to expect from a Notified Body (NB)

- Designated by an EU Competent Authority to **perform conformity assessments** (Annex VII)
- ➢ Assessment based on the evidence & conclusions provided, that the device conforms to the relevant requirements (GSPRs, Annex I)
- NB must demonstrate that it is **competent** to perform these reviews (based on IVDR (NBOG) codes

- *…shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.*

bsi. ...making excellence a habit.

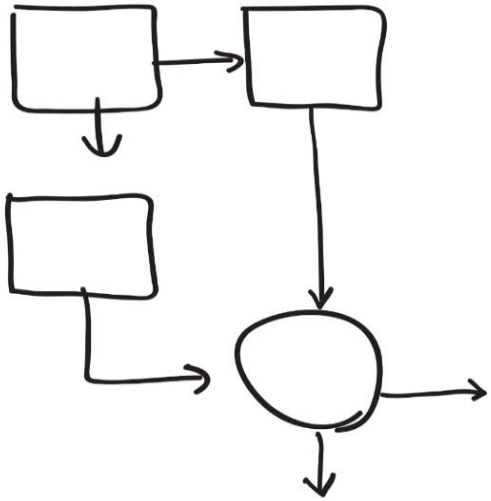
To start the conformity assessment process…

Quotation and Application

- Formal application by manufacturer to a NB
- Contract between both parties
  - Application to single NB; information about previous applications for the same device
  - Manufacturer to inform NB of vigilance reports
  - Right of a NB to suspend, restrict, or withdraw certificates
  - NB must be able to fulfil their information obligations
- Contract review by NB
  - Scope of designation
  - Competency for assessment

But when?

- NBs cannot quote or do any conformity assessment towards the IVDR until they are designated



- In meantime, keep communication open
- Check your NB's designation progress
- Check their application scope
- Share your plans
- Highlight possible borderline classification cases

Sources of information

Information updates!

- Watch for updates from Regulatory bodies
  - https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
  - camd-europe.eu
    - ✓ IVDR FAQ
- Notified bodies
  - team-nb.org
    - ✓ Designation survey
- Your industry representatives e.g. MedTech Europe

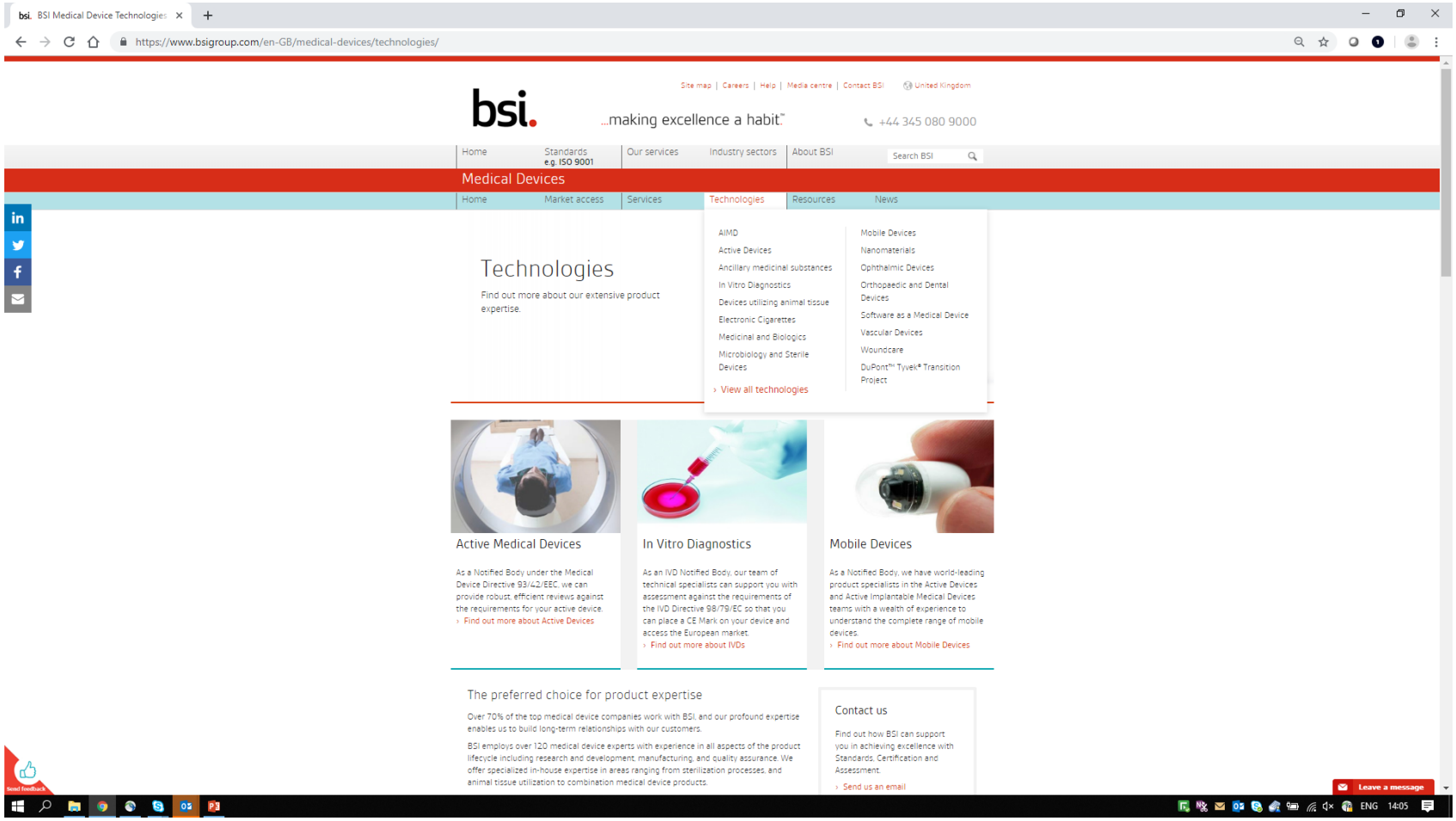
MDR/IVDR Corrigendum

Published on 13 Mar 2019; Consolidated text yet to be published in the Official Journal (as of 05Apr2019)

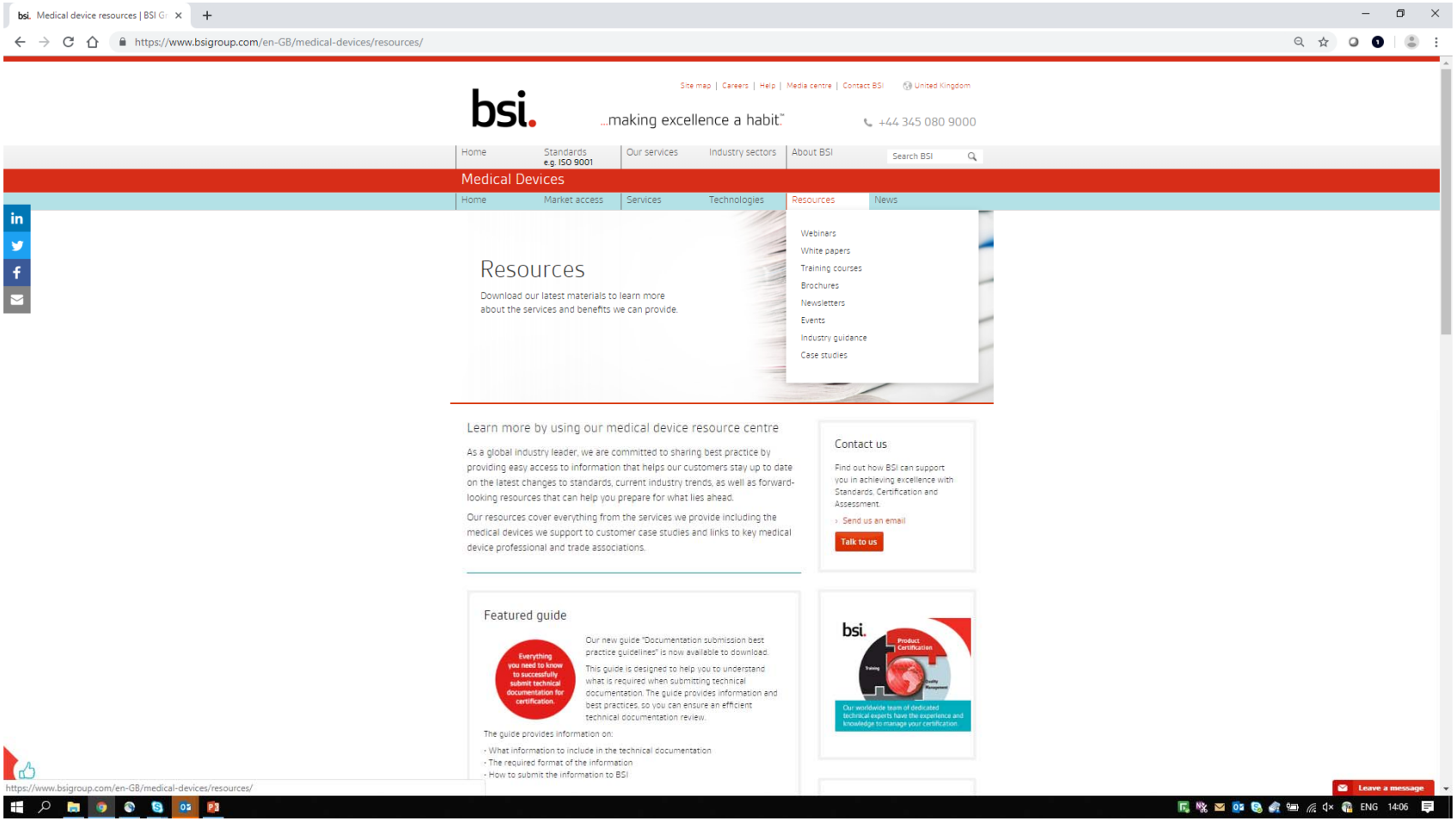
IVR Corrigendum – Key points

- Fixed many typos and un-intended omissions etc
- Reference to ISO 20916 on clinical performance studies instead of ISO 14155
- Clarified that even Class B devices require technical documentation assessment during surveillance
- Clarified that assessment of technical documentation is not limited to just clinical evidence for Class B and Class C devices. Full conformity to Annex II, III is required
- Sampling of technical documentation (Class B and Class C devices)
  - TF sampling plan should cover the entire range of devices over the certificate cycle as opposed to all devices covered by the certificate

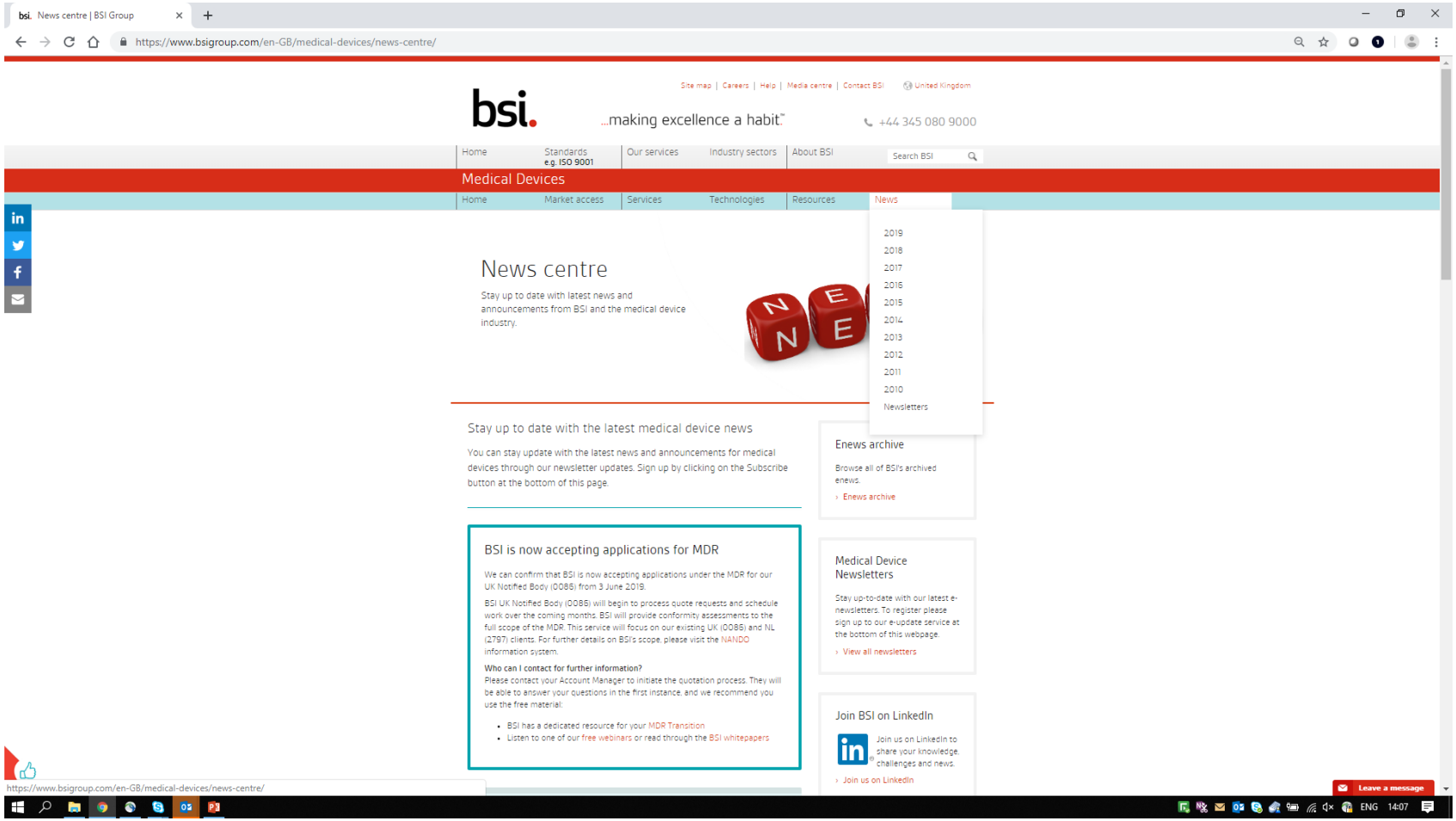
bsigroup.com/medical : Technologies



bsigroup.com/medical : Resources



bsigroup.com/medical : News



bsigroup.com/IVDR-revision

What you can do now!

Even though we are waiting for classification guidance, do not let this stop you from progressing your transition plans

- There is not much difference between Class B & Class C in requirements

- Time is critical!

- Classify
  - *If necessary,* w*ork on the 'worst case' scenario*
- Work on gap analyses
- Start interacting with a Notified Body

Questions & Answers

By Royal Charter

Name: **Erica Conway**
Title: Global Head - IVD

email: erica.conway@bsigroup.com

http://medicaldevices.bsigroup.com/
www.bsigroup.co.uk/IVDR-revision

bsi. ...making excellence a habit.