Conformity Assessemnt Procedures and notified bodies

Universita' degli studi di Trieste

Il Regolamento 2017/745: novità e sfide per istituzioni e aziende

24 March 2021 -

Maria Chiara Orlandi
Directorate-General for Health and Food Safety (DG SANTE) –
Unit B.6: Medical Devices, Health Technology Assessment

Health

European Commission

Plan of the presentation

- EU legislation on medical devices – the new Regulations
- Conformity assessment procedures
- Notified Bodies
- Designation of notified bodies and evolution of the joint assessment process
- Requirements to be met by notified bodies

European Commission

EU legislation on medical devices

Health

European Commission

EU legislation on medical devices

- **Current Directives and new Regulations**:
  - Directive 90/385/EEC on active implantable medical devices (AIMDD)
  - Directive 93/42/EEC on medical devices (MDD)

  Regulation (EU) 2017/745 on medical devices (MDR) adopted in April 2017 and entered into force in May 2017, as amended – fully applicable from **26 May 2021**

  Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD)

  Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) adopted in April 2017 and entered into force in May 2017, as amended – fully applicable from **26 May 2022**

- **Specific transitional provisions** (Articles 120 MDR and 110 IVDR)

European Commission

Objectives of the new EU legislation on medical devices

- The new Regulations on medical devices aim to:
  - establish a modernised and more **robust, transparent and sustainable EU regulatory framework on medical devices**, while ensuring free and fair trade of devices throughout the EU internal market
  - keep up with advances in science and technology, **adapting EU legislation to the significant scientific and technological progress in the sector**, while continuously accompanying and supporting innovation
  - ensure a better and consistently **high level of health and safety protection of public health** and patient safety for citizens using medical devices in Europe

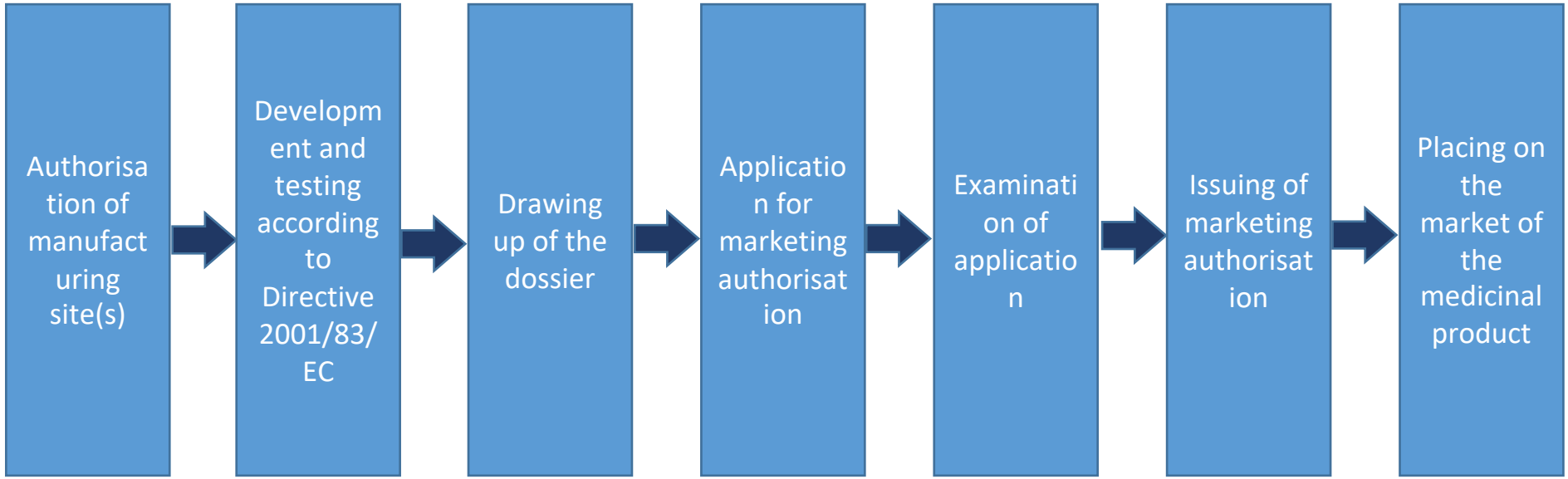
European Commission

Conformity assessment procedures

Health

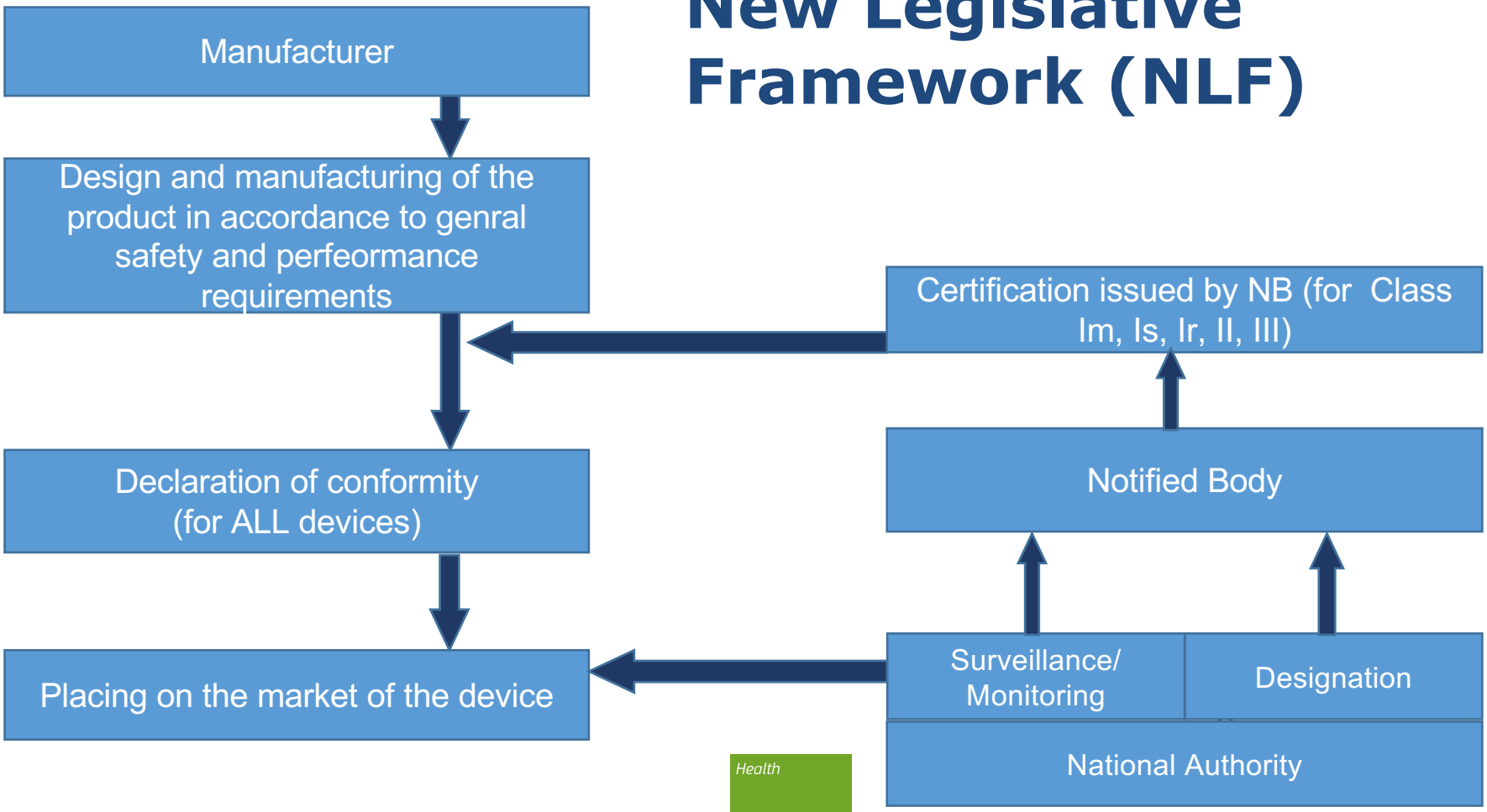
European Commission

Medicinal Products – Directive 2001/83/EC



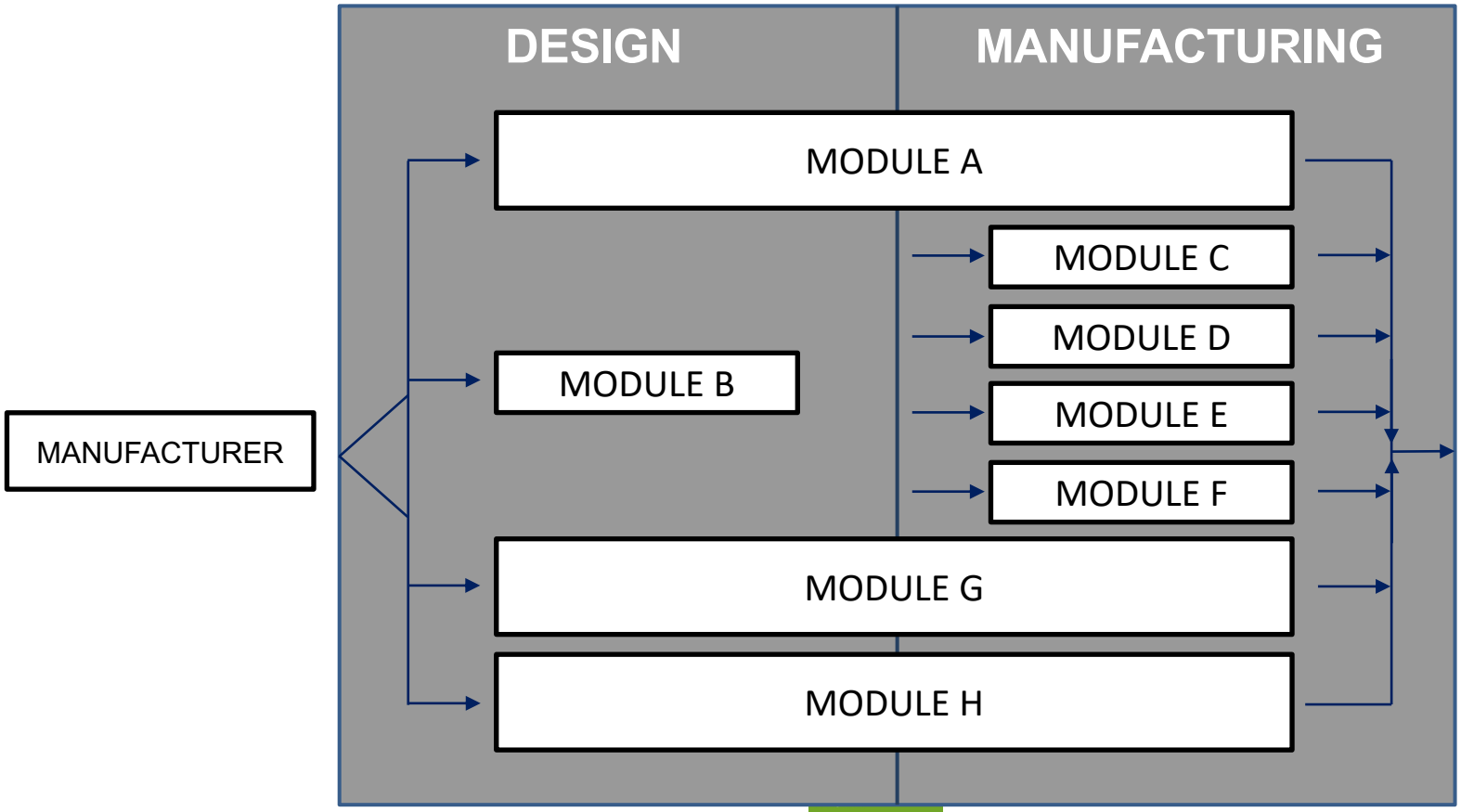
European Commission

Medical Devices - New Legislative Framework (NLF)



Health

Conformity assessment procedures - Modules



Procedures to be used when performing conformity assessment in respect of particular products as set out in Decision No 768/2008/EC (NLF)

CE

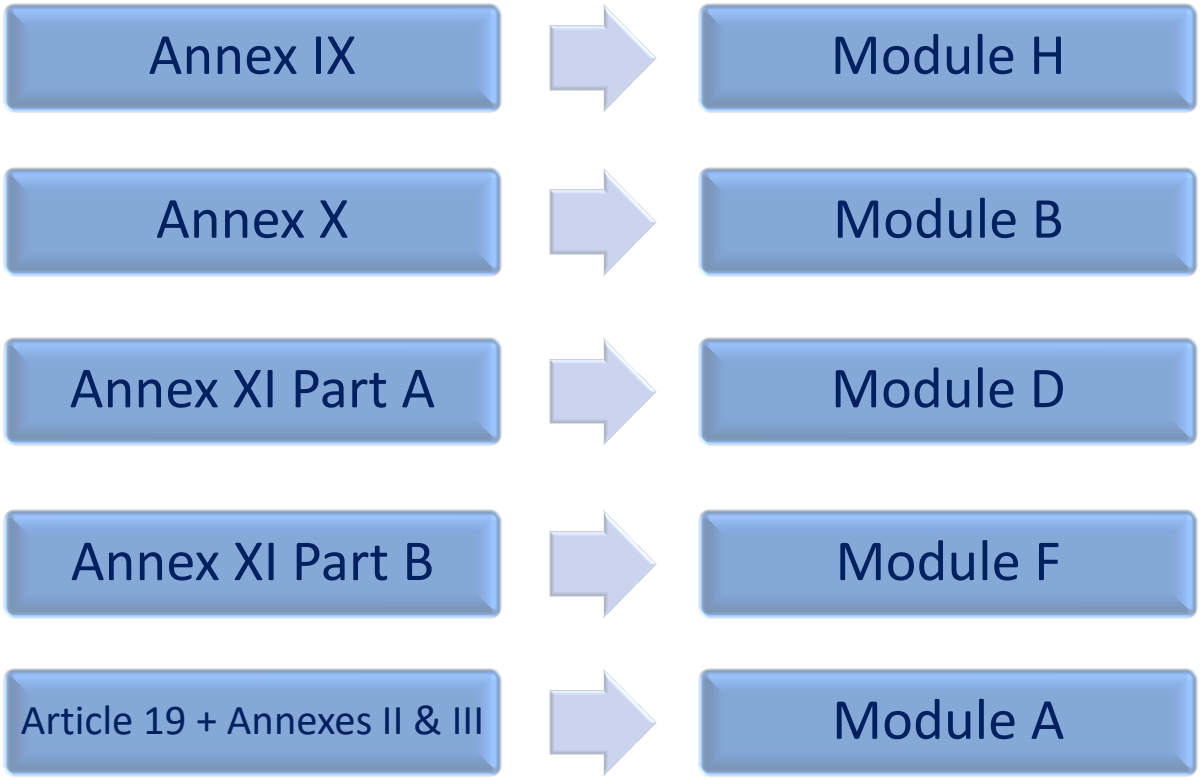
European Commission

Conformity assessment procedures: comparison MDR vs MDD

MDR Annex	Procedure	MDD Annex
Annex IX	Conformity assessment based on a quality management system and on assessment of technical documentation	Annex II
Annex X	Conformity assessment based on type-examination	Annex III
Annex XI	Conformity assessment based on product conformity verification	Annex IV & Annex V

European Commission

Conformity assessment procedures – MDR Annexes



*Match between modules set out in Decision No 768/2008/EC and Annexes of the MDR**

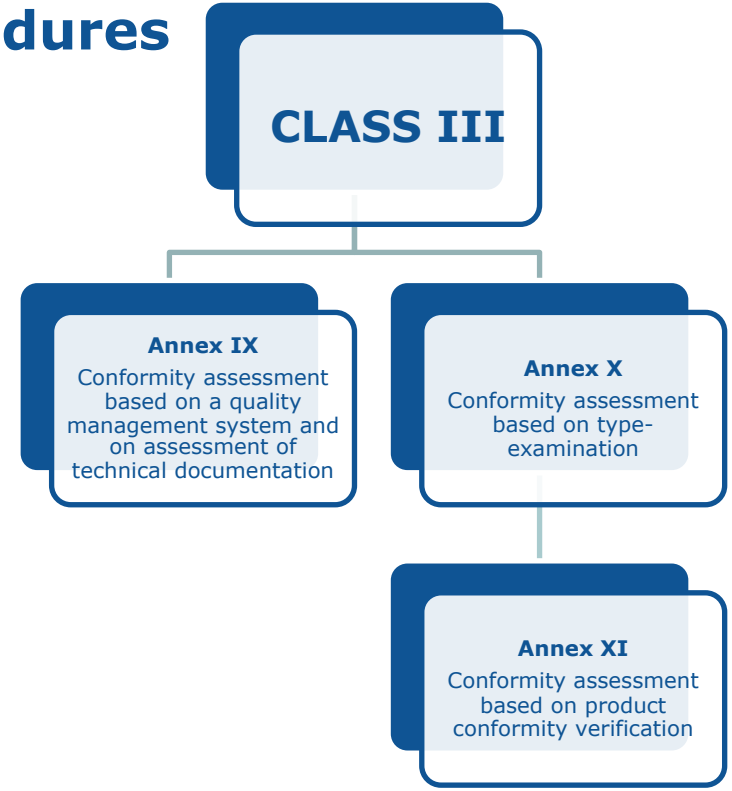
** Analogous procedures are established in the IVDR*

Conformity assessment procedures

<u>CLASS III IMPLANTABLE</u>:
Clinical Evaluation Consultation Procedure of notified body's clinical evaluation assessment report (*point 5.1 to Annex IX*)

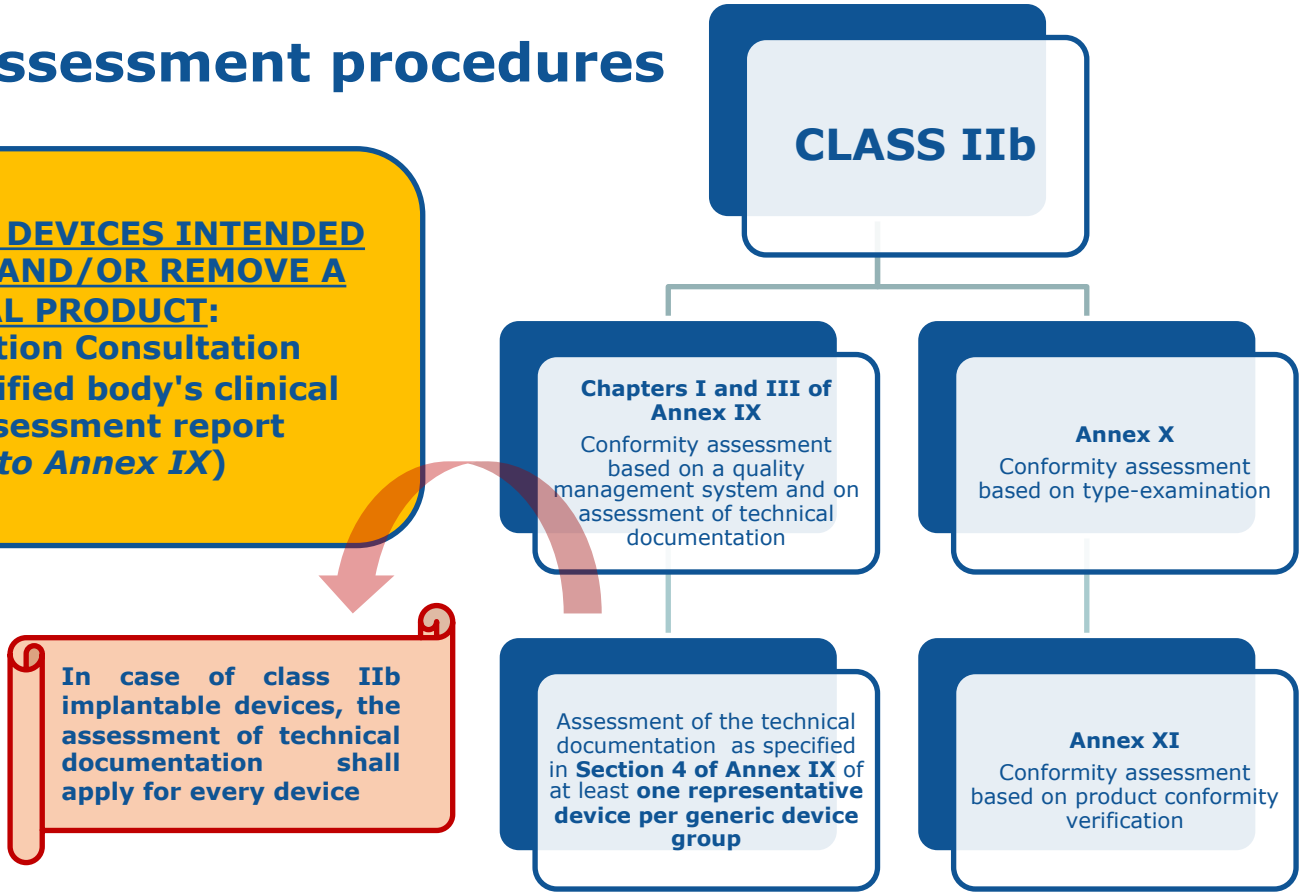
SPECIFIC ADDITIONAL PROCEDURES

- Devices incorporating a medicinal substance
- Devices manufactured utilising, or incorporating, tissues or cells of human or animal origin, **o**r their derivatives, that are non-viable or rendered non-viable
- Devices that are composed of substances or of combinations that are absorbed by or locally dispersed in the human body



Conformity assessment procedures

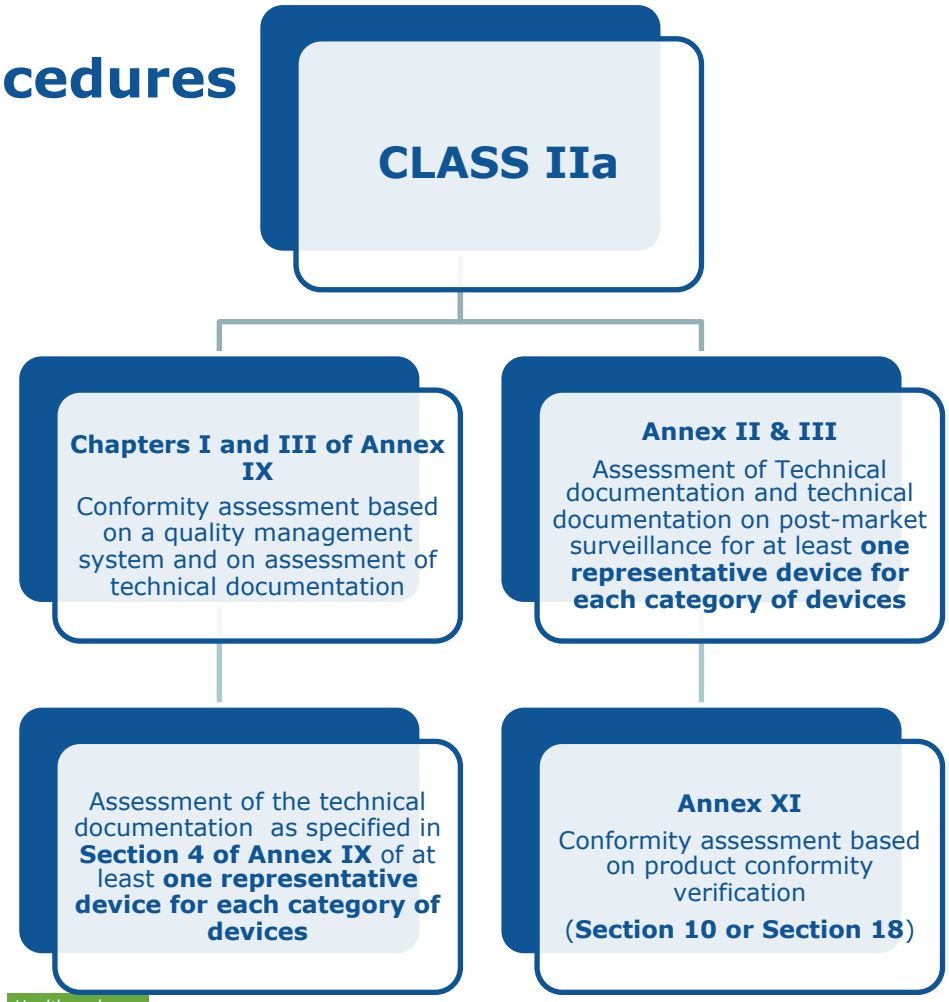
CLASS IIb ACTIVE DEVICES INTENDED TO ADMINISTER AND/OR REMOVE A MEDICINAL PRODUCT:
Clinical Evaluation Consultation Procedure of notified body's clinical evaluation assessment report (*point 5.1 to Annex IX*)



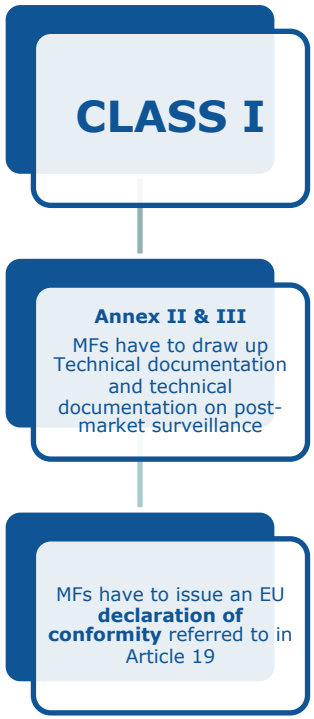
In case of class IIb implantable devices, the assessment of technical documentation shall apply for every device

European Commission

Conformity assessment procedures

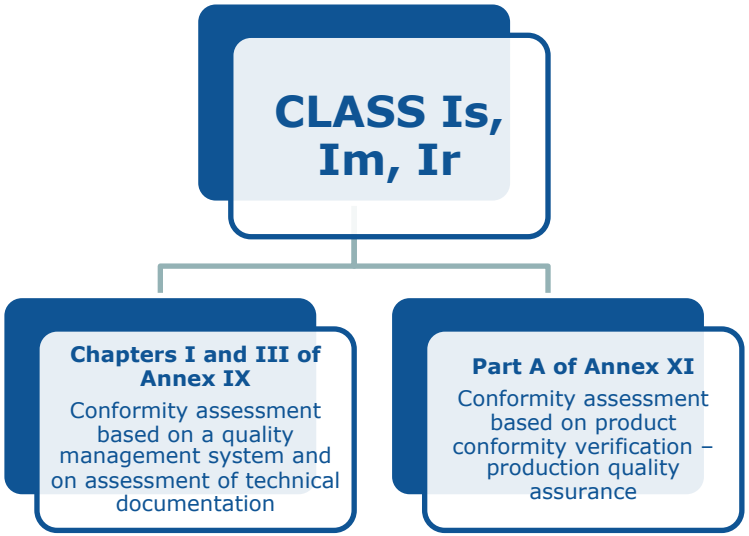


Conformity assessment procedures



… In addition, for Class I devices

- ***placed on the market in sterile conditions***
- ***having a measuring function***
- ***being reusable surgical instruments***



Notified Bodies

Health and
Food Safety

European Commission

Notified bodies (I)

For all devices but class I devices and for certain aspects relating to class I devices supplied sterile, with measuring functions or being a reusable surgical instrument, compliance of devices has to be verified by a third-party entity, named **NOTIFIED BODY**. Involvement of the notified body is proportionate to the inherent risk of the device and depends on the conformity assessment procedure followed.

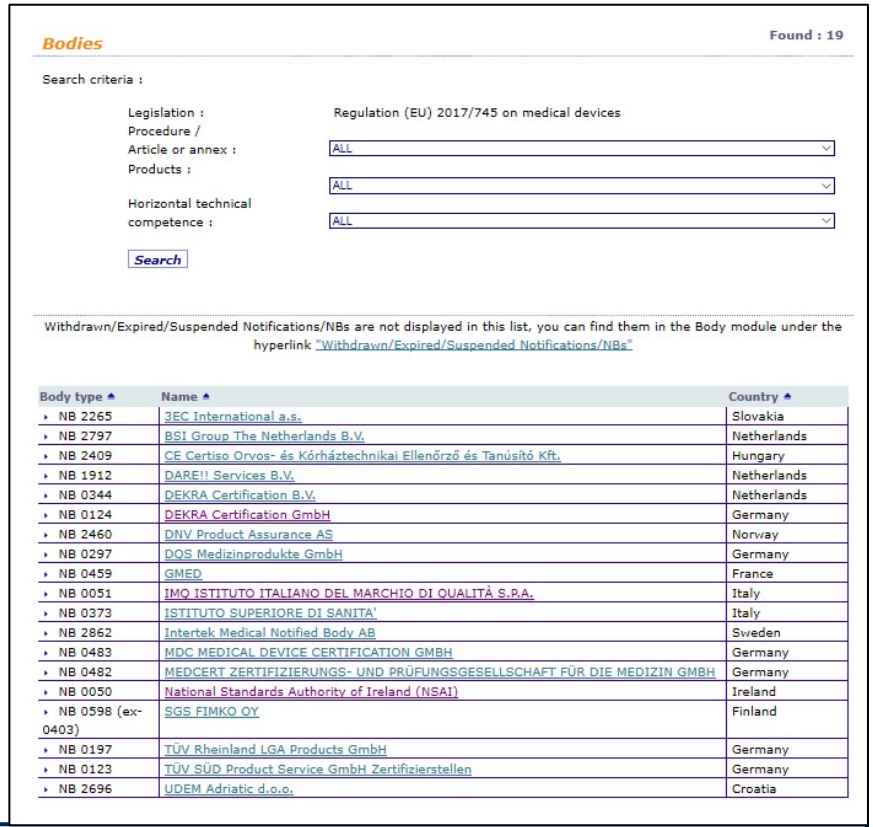
Notified Bodies are entities, either public or private, performing third-party conformity assessment activities including calibration, testing, certification and inspection according to MDR/IVDR.

European Commission

Notified bodies (II)

Notified Bodies are designated by national authorities and notified to the Commission. The Commission assign a four-digit identification number to each notified body (NB xxxx).

The lists of designated notified bodies are available in NANDO (New Approach Notified and Designated Organisations) Information System.



Bodies Found : 19

Search criteria :

Legislation : Regulation (EU) 2017/745 on medical devices
Procedure / Article or annex : ALL
Products : ALL
Horizontal technical competence : ALL

Search

Withdrawn/Expired/Suspended Notifications/NBs are not displayed in this list, you can find them in the Body module under the hyperlink "Withdrawn/Expired/Suspended Notifications/NBs"

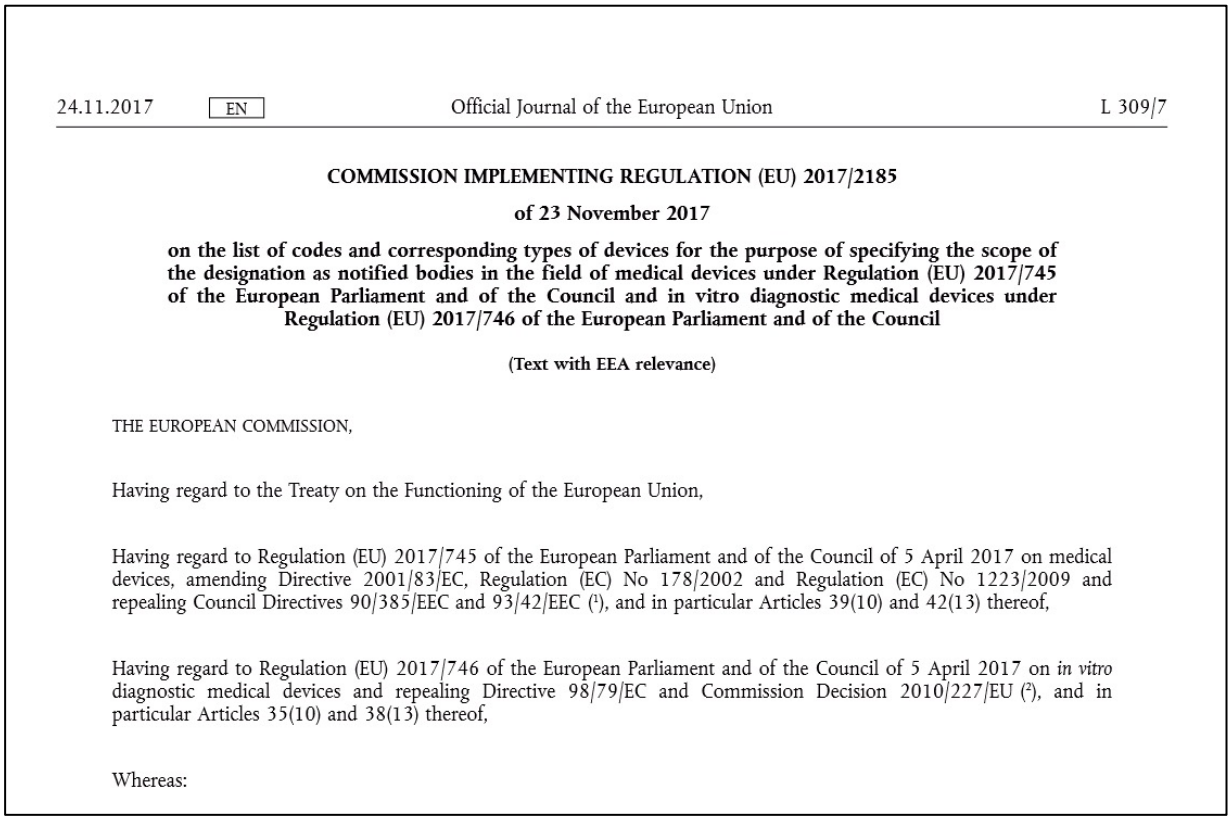
Body type	Name	Country
NB 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV Product Assurance AS	Norway
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0459	GMED	France
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Italy
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0598 (ex-0403)	SGS FIMKO OY	Finland
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany
NB 2696	UDEM Adriatic d.o.o.	Croatia

- **List of notified bodies under the MDR**
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
- **List of notified bodies under the IVDR**
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

European Commission

Notified bodies (III)

Notified Bodies are designated to carry out conformity assessment activities for specific types of devices, as specified in Commission Implementing Regulation (EU) 2017/2185.



24.11.2017 EN Official Journal of the European Union L 309/7

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185

of 23 November 2017

on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (1), and in particular Articles 39(10) and 42(13) thereof,

Having regard to 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 (2), and in particular Articles 35(10) and 38(13) thereof,

Whereas:

Notified bodies (IV)

How a designation/notification under the MDR looks like

Notification of a Body in the framework of a technical harmonization directive

From : Ministero dello Sviluppo Economico - Direzione Generale per il Mercato, la Concorrenza, il Consumatore, la Vigilanza e la Normativa Tecnica
Via Sallustiana, 53
00187 ROMA
Italy

To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

Reference : Legislation : Regulation (EU) 2017/745 on medical devices

Body name, address, telephone, fax, email, website :

IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.
Via Quintiliano, 43
20138 - MILANO
Italy
Phone : +39 02 50731
Fax : +39 02 50991500
Email : info@imq.it
Website : www.imq.it

Body : **NB 0051**

Tasks performed by the Body :

Last approval date : 20/08/2019

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
- A. Active devices			
- 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management	Annex X Annex IX(I) Annex IX(II)	

European Commission

Designation of notified bodies and evolution of joint assessment process

Health

European Commission

Designation of notified bodies

Critical role in the regulation of medical devices

Designated by a MS

Assessors from National & European Authorities

Scope of designation based upon codes

NANDO (database of NBs)

Manufacturers should verify if:

- **your NB will be / is designated under the Regulations**
- **the scope of its designation will cover all your products**

European Commission

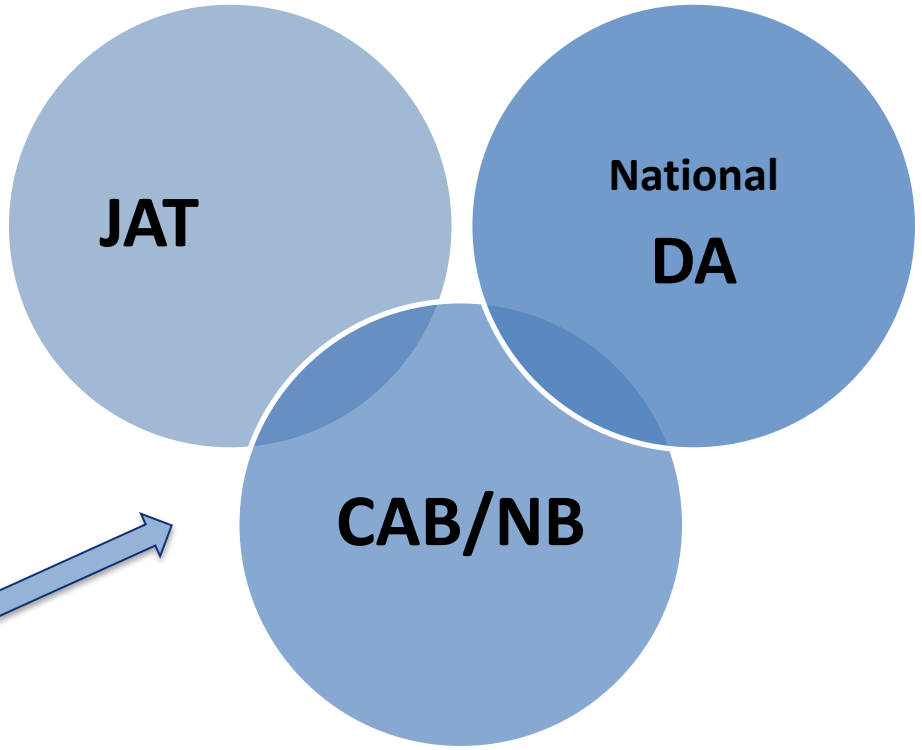
Evolution of the joint assessment process

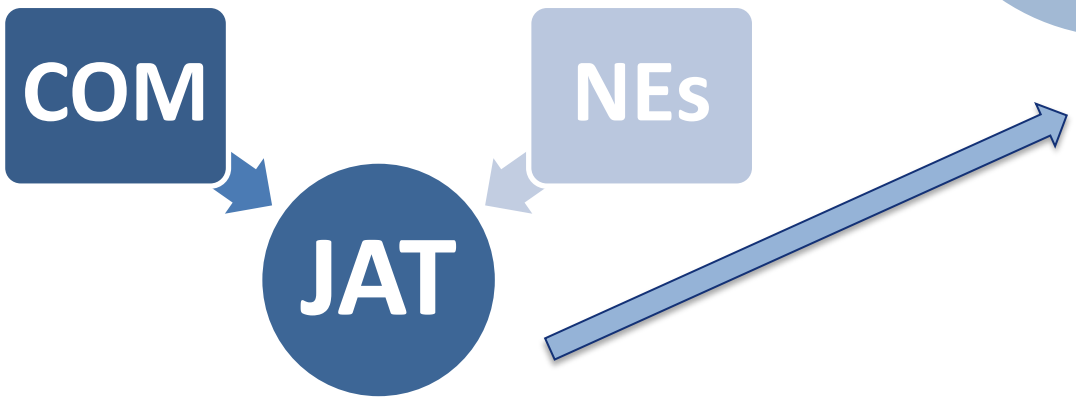
- Voluntary process established in 2013
- Mandatory process in IR 920/2013
- Stricter requirements under the MDR and IVDR:
  - Art 38-42 MDR and 34-38 IVDR
  - Implementing acts on codes
  - NBOG BPG 2017-1 on designation and notification

European Commission

Actors in the joint assessment

- Harmonisation
- Uniform application of legislation
- Fosters cooperation and sharing of best practice





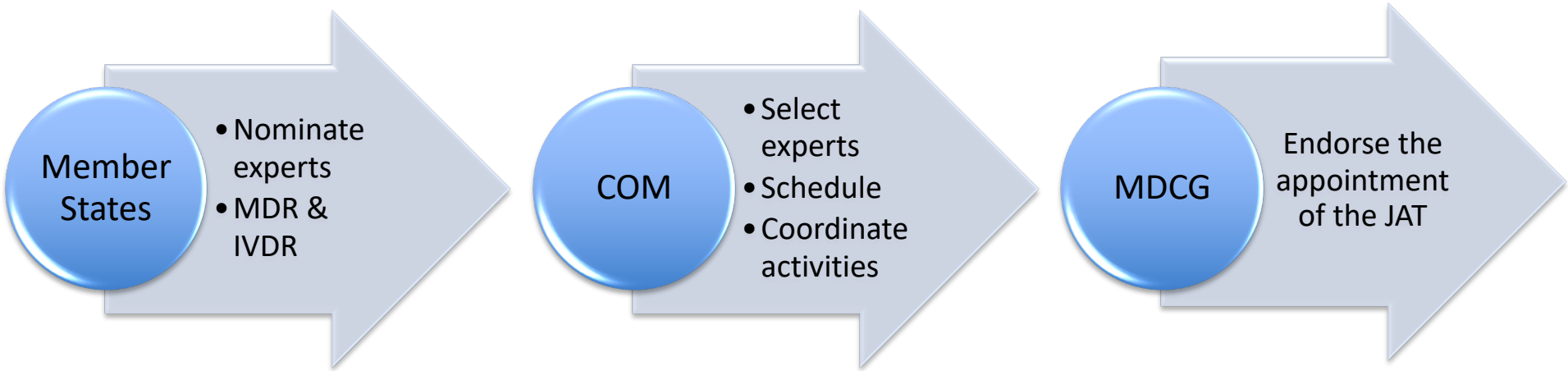
CAB: Conformity Assessment Body
JAT: Joint Assessment Team
MDCG: Medical Device Coordination Group
COM: Commission
DA: Designating Authority
NE: National Expert

European Commission

Appointment of a Joint Assessment Team

National Experts chosen based upon:
- Expertise / Competence
- Availability

Scheduling linked to availability of
- CAB
- DA
- JAT



Joint assessment objectives

1. Determine if the CAB/NB

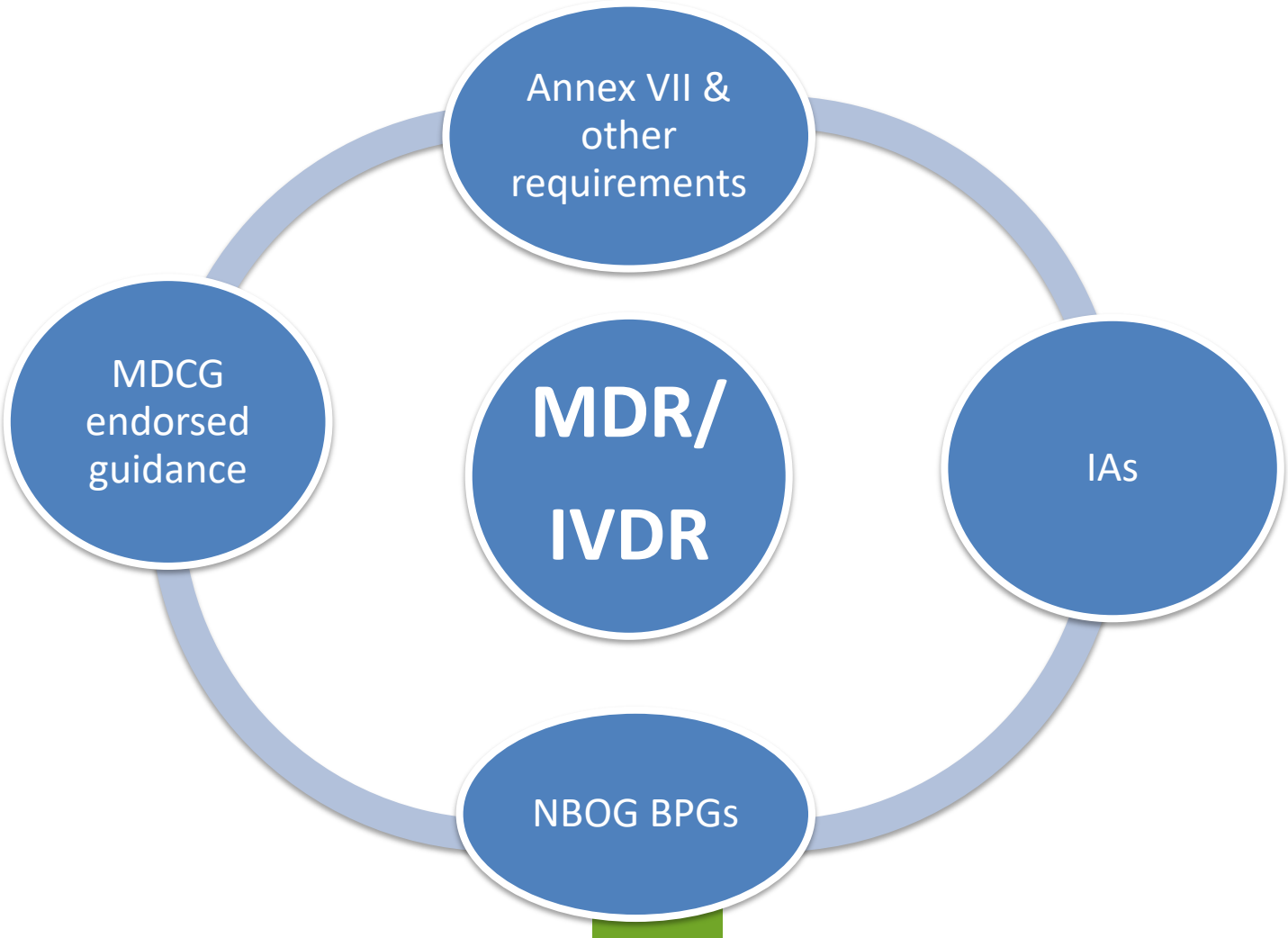
- Fulfills the criteria for designation
- Still fulfills the criteria

2. Provide a Recommendation

- For designation
- Continues to satisfy the requirements

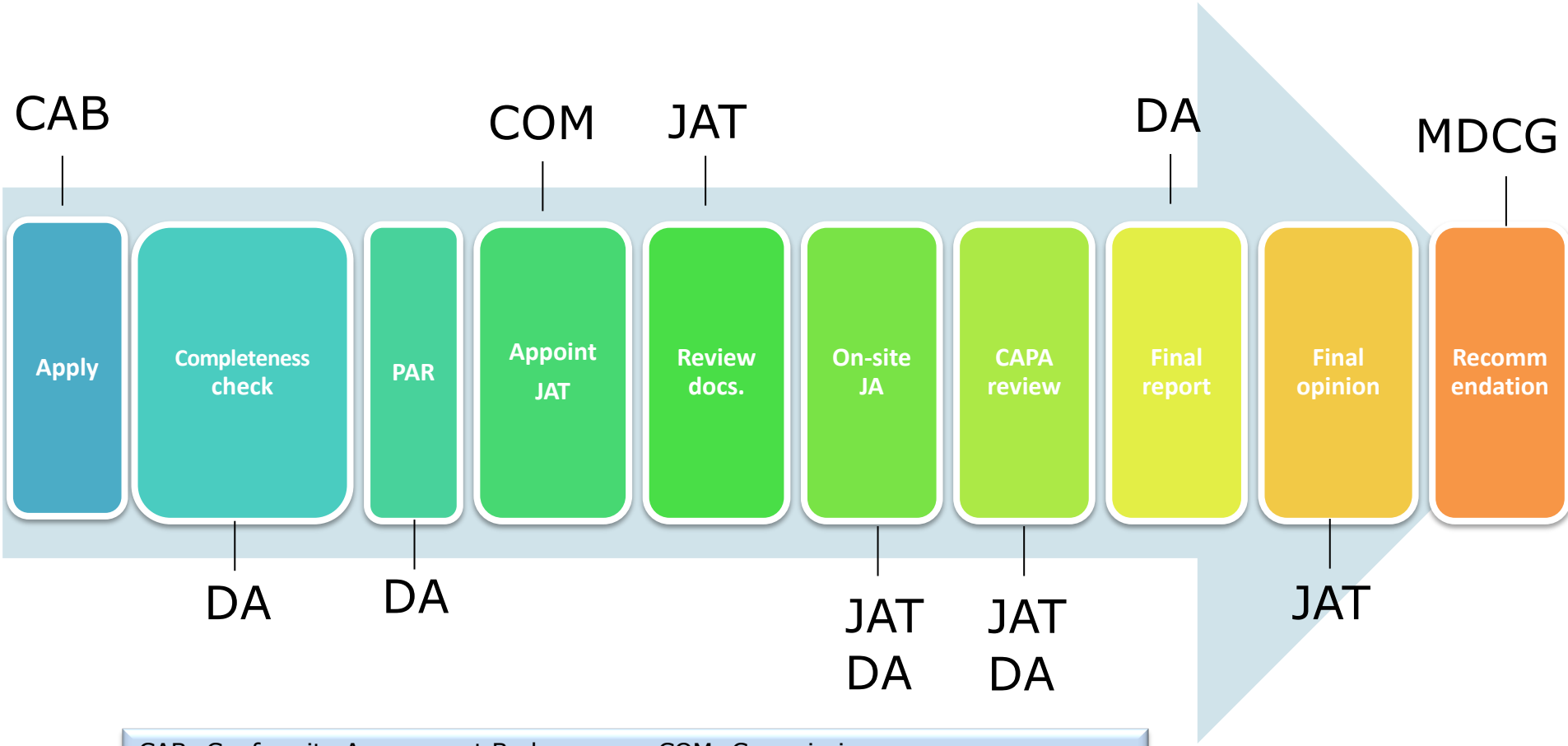
European Commission

Joint assessments: criteria



European Commission

Joint assessments process



CAB: Conformity Assessment Body
JAT: Joint Assessment Team
MDCG: Medical Device Coordination Group
COM: Commission
DA: Designating Authority
PAR: Preliminary Assessment Report

European Commission

Notification process

- Articles 42 MDR & 38 IVDR
- DA will notify COM and Member States including monitoring activities
- 28 days for objections
- 42 days for publication

European Commission

Requirements to be met by notified bodies

Health

European Commission

Requirements established by Annex VII of the MDR/IVDR

- Organisational and general requirements
- Quality management requirements
- Resources requirements
- Process requirements

European Commission

Organisational and general requirements

- Legal status and organizational structure
- Independence and impartiality
- Confidentiality
- Liability
- Financial requirements
- Participation in coordination activities

European Commission

Quality management requirements

NB to **establish, document, implement, maintain and operate a quality management system that is appropriate** to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating the **consistent fulfilment** of the requirements of the Regulation

Minimum elements to be addressed by the quality management system, including management system structure and documentation; policies for assignment of activities and responsibilities to personnel; assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management; the planning, conduct, evaluation and, if necessary, adaptation of its conformity assessment procedures; control of documents and records; management reviews; internal audits; corrective and preventive actions; complaints and appeals; and continuous training

European Commission

Resources requirements (I)

General requirements

- Necessary personnel in the specific field
- Permanent availability of personnel
- Sufficient number
- Sufficient internal competence
- Possess or have access to all equipment and facilities

Qualification criteria in relation to personnel

- For **selection and authorisation** of persons involved in the conformity assessment
- Including **knowledge, experience, training and other competence** required
- Various functions covered

European Commission

Resources requirements (II)

Documentation of qualification, training and authorization of personnel

- Qualification of **each member of personnel involved in the conformity assessment activities** and the satisfaction of qualification criteria to be fully documented
- **Matrix detailing adequate and clear rationale** for the authorization and responsibility of personnel involved in the conformity assessment

Subcontractors and external experts

- Certain component part of the conformity activities may be subcontracted but specific activities, including decision making, not to be subcontracted
- Policy describing conditions under which subcontracting may take place

Monitoring of competence, training and exchange of experience

- Procedure for initial evaluation and on-going monitoring of personnel
- Competence of personnel to be reviewed at regular intervals

European Commission

Process Requirements (I)

- Notified body quotation and pre-application activities
- Application review and contracts
- Allocation of resources
- Conformity assessment activities
- Reporting

European Commission

Process Requirements (II)

- Final review
- Decisions and certifications
- Changes and modifications
- Surveillance activities and post-certification monitoring
- Re-certification

Links and references - horizontal

- Single market for goods https://ec.europa.eu/growth/single-market/goods
- New legislative framework https://ec.europa.eu/growth/single-market/goods/newlegislative-framework
- The "Blue Guide" on the implementation of EU product rules https://ec.europa.eu/docsroom/documents/18027
- CE marking https://ec.europa.eu/growth/single-market/ce-marking/
- Conformity assessment https://ec.europa.eu/growth/single-market/goods/building-blocks/conformity-assessment
- Market surveillance for products https://ec.europa.eu/growth/singlemarket/goods/building-blocks/market-surveillance
- NANDO (New Approach Notified and Designated Organisations) information system https://ec.europa.eu/growth/tools-databases/nando
- Harmonised standards https://ec.europa.eu/growth/single-market/europeanstandards/harmonised-standards

Links and references - vertical

- Medical Devices - Sector https://ec.europa.eu/health/md_sector/overview
- Medical Devices - New Regulations
  - overview https://ec.europa.eu/health/md_newregulations/overview
  - guidance https://ec.europa.eu/health/md_sector/new_regulations/guidance
  - publications/factsheets https://ec.europa.eu/health/md_newregulations/publications
- MDR/IVDR implementation rolling plan https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_rolling-plan_en.xlsx
- MDCG in the "Register of Commission expert groups and other similar entities" https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565

Contact:

European Commission –
Directorate-General for Health and Food Safety (DG SANTE)
– *Unit B.6: Medical Devices, Health Technology Assessment*

SANTE-MED-DEV@ec.europa.eu

European Commission