Classification & major requirements of in-vitro diagnostics under IVDR

Evnia
To Strive · To Seek · To Find

Overview of IVDR Classification [Consult MDCG 2020-16]

- Under IVDR, IVDs will be graded into 4 categories based on the risk they pose to health and safety, starting with the lowest risk category at Class A, up to the highest at Class D.
- Manufacturer proposes the classification based on the intended purpose. A notified body shall verify this proposal for classes A sterile, B, C, and D
- In case of a dispute, national Competent Authorities arbitrate

- IVDR divides in-vitro diagnostic products into further categories:
  - ✓ devices for near-patient testing
  - ✓ devices for self-testing
  - ✓ companion diagnostic devices which are essential for the safe and effective use of a corresponding medicinal product.
- IVDR expands the definition of an IVD to encompasses software which is specifically intended to be used for a purpose set out in the definition of an IVD.

Note: software used merely for general purpose, even if in a healthcare setting or for well-being purposes, does not meet the definition of an IVD.

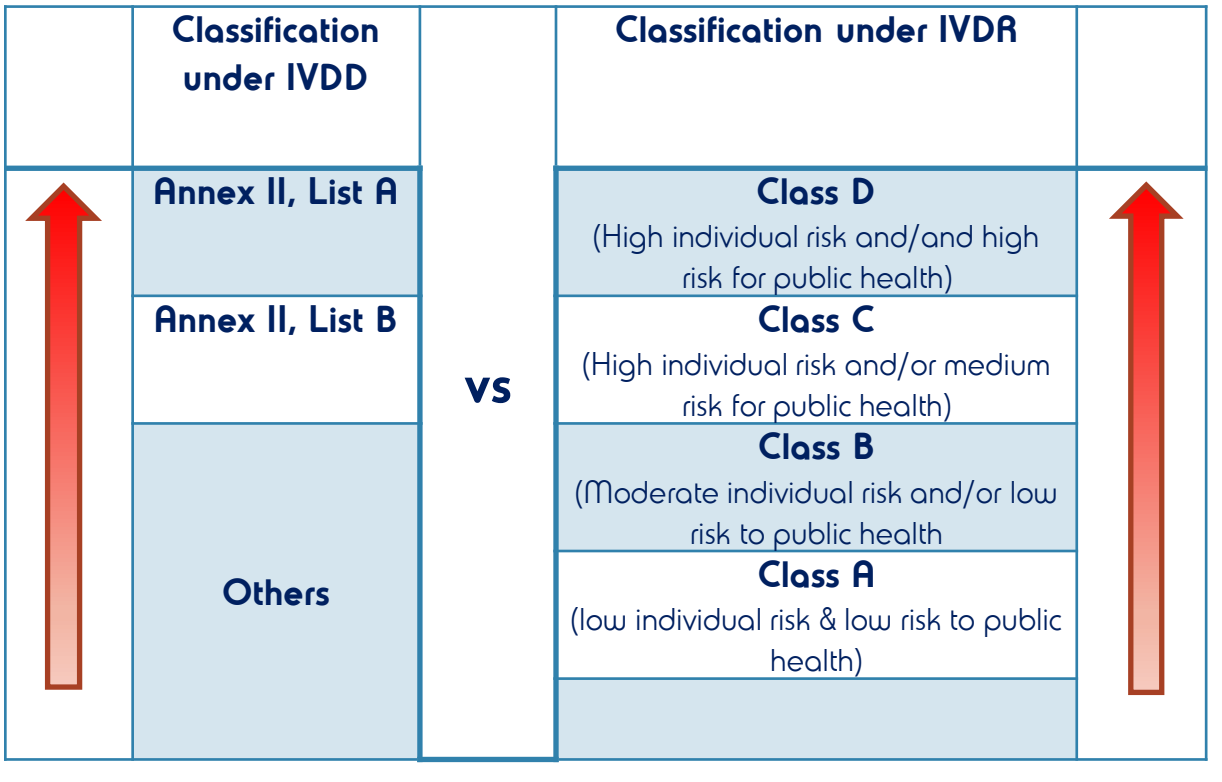
- Online sale of IVDs: IVDs and testing services marketed online and being accessible to European citizens must comply with the IVDR the moment they are offered for use in the EU.

Special comments. Refer to MDCG 2020-16

- **Application of the classification rules shall be governed by the intended purpose of the devices.**
- Rule 3: It may be possible for a device to fall under more than one indent. Where this is the case, the most appropriate indent should always be applied, based on the intended purpose of the device
- If a device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
- Rule 4: When a device simultaneously detects a marker that falls under two different rules, leading to a different classification, then the highest class prevails for the whole device
- Accessories for an in vitro diagnostic medical device shall be classified in their own right separately from the device with which they are used.
- Rule 5:
  - ✓ Accessories are considered devices if they possess one or more specific characteristics to specifically enable an IVD to be used in accordance with its intended purpose or to assist the medical functionality of the IVD
  - ✓ If a laboratory instrument has an independent measuring function, which does not use any additional reagents, it is classified according to the intended purpose of the analysis
- Software, which drives a device or influences the use of the device shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right (Regulation (EU) 2017/746; Annex VIII 1.4). Consult: MDCG 2019-11

Classification & major requirements of in-vitro diagnostics under IVDR

Overview of IVDR Classification - [Consult MDCG 2020-16]



Attention!

- The only self-certified devices are the ones falling under Rule 5 (e.g. products for general laboratory use, buffers, general culture media, histological stains, instruments for IVD procedures and specimen receptacles)
- Products falling under Rule 6 (i.e. the ones not covered by any other Rule) require Notified Body certification
- Companion diagnostics will be classified either as C or D devices. Consultation procedure required according to the selected conformity assessment route (Annex IX Section 5.2 or Annex X Section 3(k)

Rule	Device intention	Typical classification*
Rule 1	To detect transmissible agents of a life-threatening disease where it is critical for patient management or where the disease has a high risk or suspected high risk of propagation	Class D
Rule 2	To be used for blood grouping or tissue typing for the purposes of transfusion or transplantation	Class B/Class D
Rule 3	To detect, screen and manage various infectious diseases including for example; detecting the presence of a sexually transmitted agent, pre-natal screening and management of patients suffering from a life-threatening condition	Class C
Rule 4	For self-testing	Class B/Class C
Rule 5	Products for general laboratory use	Class A
Rule 6	Devices not covered in Rules 1 – 5	Class B
Rule 7	Devices which are controls without a quantitative or qualitative assigned value.	Class B

** Classification may vary based on the particular characteristics of an IVD

Classification & major requirements of in-vitro diagnostics under IVDR

Evnia
To Strive • To Seek • To Find

Universal requirements for classification applicable to all IVDs

Classification

- ✓ must be justified and be part of Technical Documentation (see Annex II, Section 1.1f)
- ✓ Classification must be stated on the declaration of conformity (see Annex IV, Section 5)
- ✓ Registration in Eudamed accompanied with risk classification (see Annex VI, Part A, Section 2.8)
- ✓ QMS must include classification (see Art. 10.8 & Annex IX, Chapter I, Section 2.2c)
- ✓ Certificates of the Notified Bodies must mention classification (see Annex XII, Chapter I, Section 4)
- ✓ Must be taken into account for Post-Market Surveillance activities (see Art. 78.1)
- ✓ Must be taken into account in Performance Evaluations (see Annex XIII, Part A, Section 1)

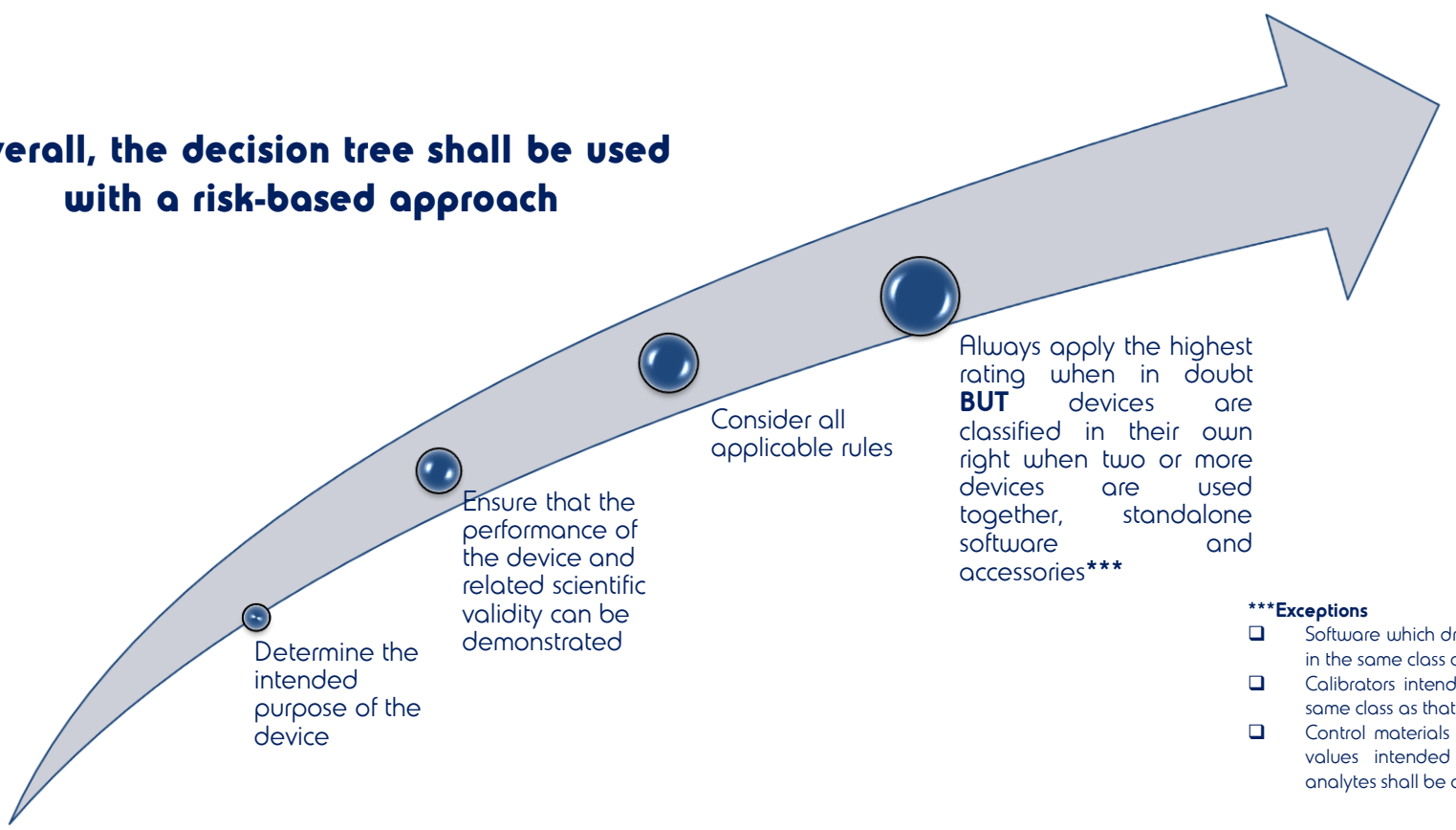
Device-specific requirements based on classification

Class	Device-Specific Requirements
Class A	❑ PMS Report to be updated when necessary and to be available for NBs and CAs upon request (see Art. 80) ❑ Single-use devices: the UDI carrier can be on a multi-unit packaging instead of individual unit packaging (see Annex VI, Part C, Section 4.3) ❑ Implementation of the UDI carrier labelling: 26 May 2027
Class B	❑ PMS Report to be updated when necessary and to be available for NBs and CAs upon request (see Art. 80) ❑ Single-use devices: the UDI carrier can be on a multi-unit packaging instead of individual unit packaging (see Annex VI, Part C, Section 4.3) ❑ Economic Operators: when registering to EUDAMED, they must indicate to the Member States where they intent to market the device (see Annex VI, Part A, Section 2.4) ❑ Implementation of the UDI carrier labelling: 26 May 2025
Class C	❑ A summary of safety and performance (SSCP) is mandatory (see Art. 29.1) and should be uploaded to EUDAMED (see Annex VI, Part A, Section 2.11) ❑ A PSUR prepared for each device (and where relevant for each category or group of devices) to be available for NBs and CAs upon request (see Art. 81.1 & 81.3) ❑ Performance Evaluation Reports to be updated at least annually (see Art. 56.6) ❑ Economic Operators: when registering to EUDAMED, they must indicate to the Member States where they intent to market the device (see Annex VI, Part A, Section 2.4) ❑ Coordinated assessment of performance studies carried out in more than one Member State may be further prolonged by 50 days (see Art. 74.6) ❑ Member States may request designation of reference laboratories for the verification of the performance claimed by the manufacturer (see Art. 100.3) ❑ Implementation of the UDI carrier labelling: 26 May 2025
Class D	❑ A summary of safety and performance (SSCP) is mandatory (see Art. 29.1) and should be uploaded to EUDAMED (see Annex VI, Part A, Section 2.11) ❑ A PSUR must be submitted electronically to the NB via Eudamed where the NB must file its evaluation of the PSUR (see Art. 81.2) ❑ Performance Evaluation Reports to be updated at least annually (see Art. 56.6) ❑ Economic Operators: when registering to EUDAMED, they must indicate to the Member States where they intent to market the device (see Annex VI, Part A, Section 2.4) ❑ Designated EU reference laboratories will be able to verify the performance claimed by the manufacturer (see Art. 48.5) and test samples (see Art. 100.2) ❑ Special scrutiny of conformity assessment is provisioned (see Art. 50) ❑ Coordinated assessment of performance studies carried out in more than one Member State may be further prolonged by 50 days (see Art. 74.6) ❑ Member States may request designation of reference laboratories for the verification of the performance claimed by the manufacturer (see Art. 100.3) ❑ Implementation of the UDI carrier labelling: 26 May 2023

Implementing Rules under IVDR

ANNEX VIII – IMPLEMENTING & CLASSIFICATION RULES	
Part 1. Implementing Rules	How to apply Classification Rules (outlined in Annex VIII-part 2) - **Refer to MFCG 2020-16**
1.1. Application of the classification rules shall be governed by the **intended purpose** of the devices.	Classification is **determined solely by the intended purpose** of the devices
1.2. If the **device in question is intended to be used in combination with another device**, the classification rules shall apply separately to each of the devices.	Classification rules are **applicable to each device separately**
1.3. **Accessories for an in vitro diagnostic medical de**vice shall be classified in their own right separately from the device with which they are used.	▪ Accessories are **classified separately** regardless of the device they are used with ▪ Accessories are considered devices if they possess one or more specific characteristics to specifically enable an IVD to be used in accordance with its intended purpose or to assist the medical functionality of the IVD. ▪ If a laboratory instrument has an independent measuring function, which does not use any additional reagents, it is classified according to the intended purpose of the analysis.
1.4. **Software, which drives a device or influences the use of a device**, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.	Falls **into the same class** as the device
1.5. **Calibrators** intended to be used with a device shall be classified in the same class as the device.	Falls **into the same clas**s as the device
1.6. **Control materials** with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.	Falls **into the same class** as the device
1.7. The manufacturer shall take into consideration all classification and implementation rules in order to establish the **proper classification** for the device.	**All** classification and implementation rules **shall** be considered
1.8. Where a manufacturer states **multiple intended purposes** for a device, and as a result the device falls into more than one class, it shall be classified in the higher class.	Always classify into the **higher class**
1.9. If **several classification rules apply** to the same device, the rule resulting in the higher classification shall apply.	Always classify into the **higher class**
1.10. Each of the classification rules shall apply to **first line assays, confirmatory assays and supplemental assays**.	**Each classification rule** shall apply

Overall, the decision tree shall be used with a risk-based approach



***Exceptions**

- ❑ Software which drives or influences the use of a device falls in the same class as that device
- ❑ Calibrators intended to be used with a device fall in the same class as that device
- ❑ Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.