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20 Jahre 2002 - 2022

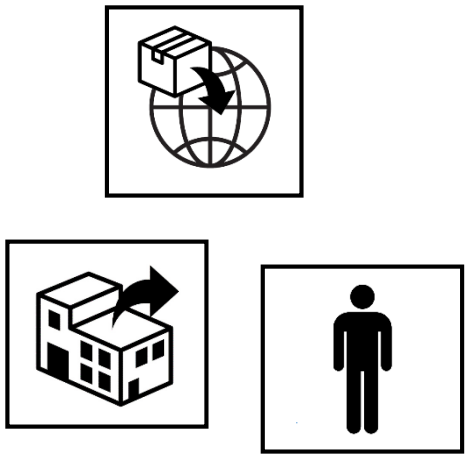
Manufacturer

Obligations and transitional provisions for Swiss manufacturers

Dr Michael Köhli, Unit Head, Medical Devices Surveillance (MDS)

A natural or legal person who […] markets [a] device under its name or trademark [...]

Definition of manufacturer, Art. 4 para. 1 let. e IvDO



Making available of a device under own name

Change of intended purpose

Change that **could** affect the conformity of the device

The quality management system includes a concept of regulatory compliance

Art. 43 IvDO, Art. 10 para. 8 let. a IVDR

Quality management system

Device conformity

Manufacturer's obligations

Post-market surveillance system

Transparency

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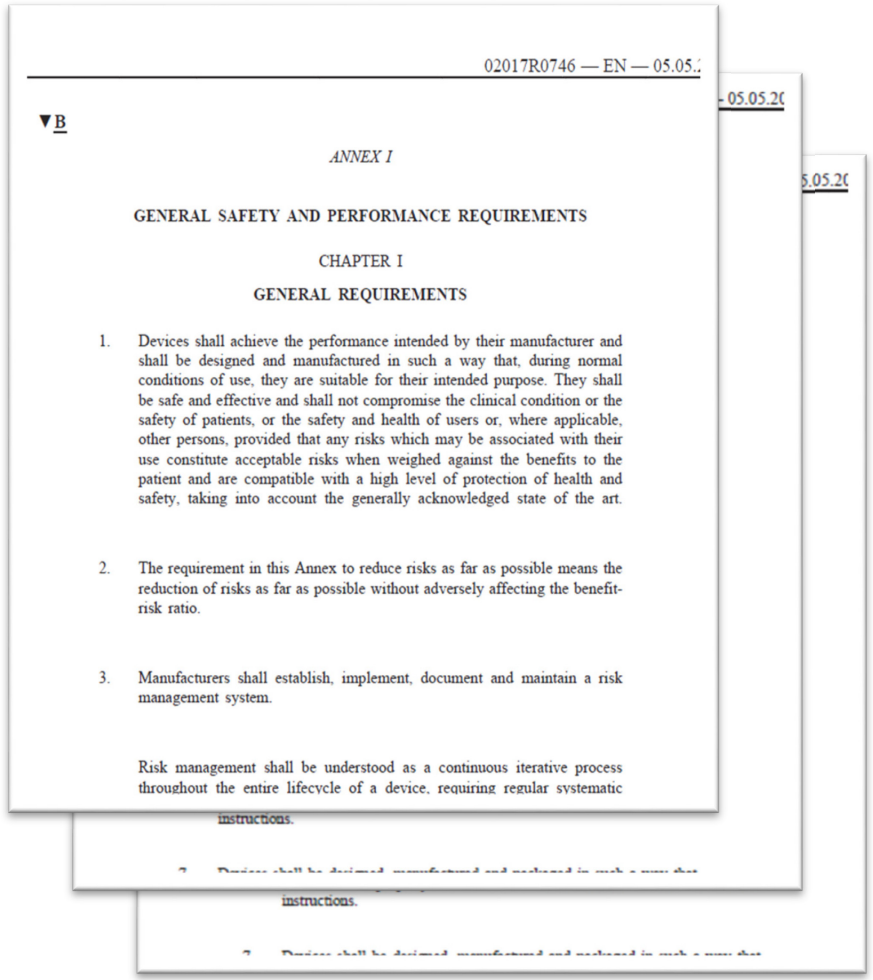
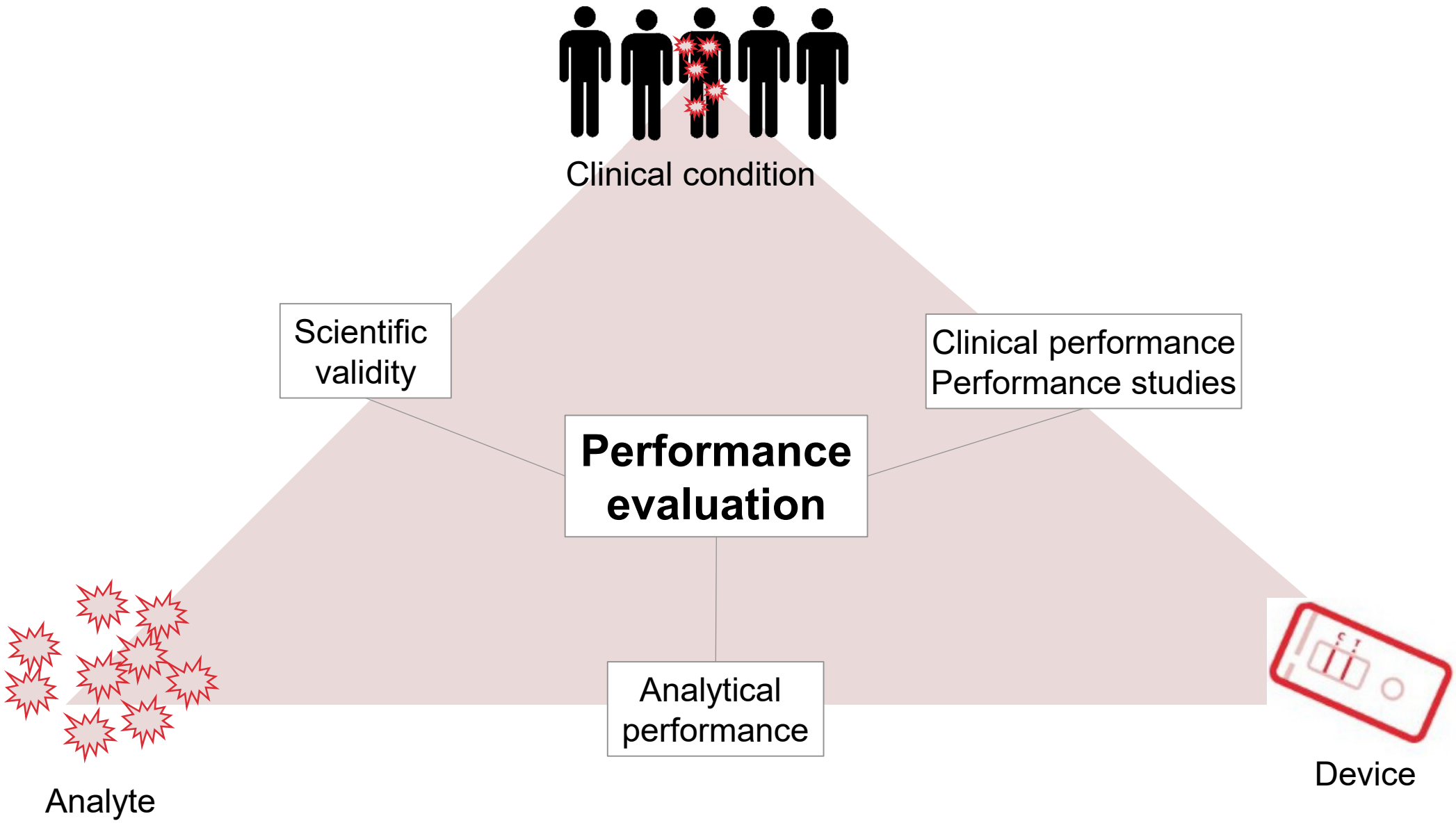
Common specifications (CS)
Designated standards
Pharmacopoeia



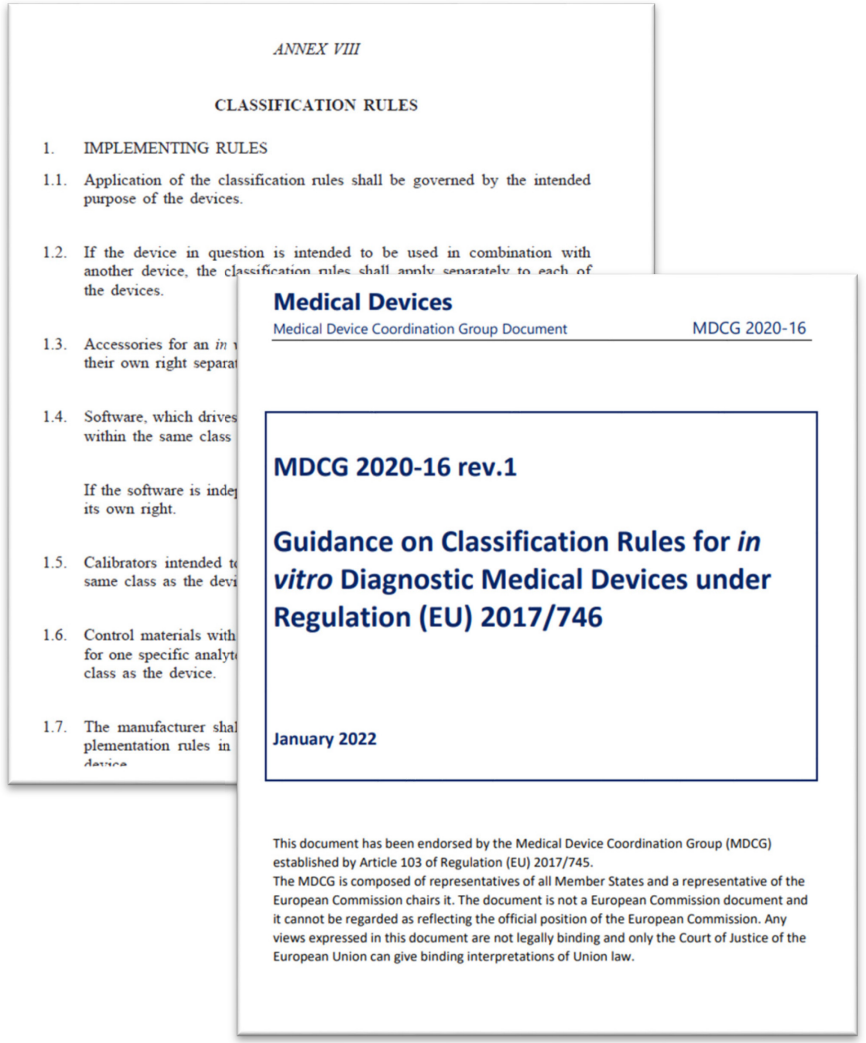

Clinical condition
Scientific validity
Clinical performance
Performance studies
Performance evaluation
Analytical performance
Analyte
Device

A manufacturer must carry out a **conformity assessment procedure**

The manufacturer and importer must be able to prove that
- a conformity assessment procedure has been carried out
- the device conforms

Conformity assessment principle Art. 17 para. 2 IvDO

Intended use



ANNEX VIII

CLASSIFICATION RULES

1. IMPLEMENTING RULES

1.1. Application of the classification rules shall be governed 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.

1.3. Accessories for an *in* their own right separat

1.4. Software, which drives within the same class

If the software is inde its own right.

1.5. Calibrators intended t same class as the devi

1.6. Control materials with for one specific analyt class as the device.

1.7. The manufacturer shal plementation rules in device

Medical Devices

Medical Device Coordination Group Document MDCG 2020-16

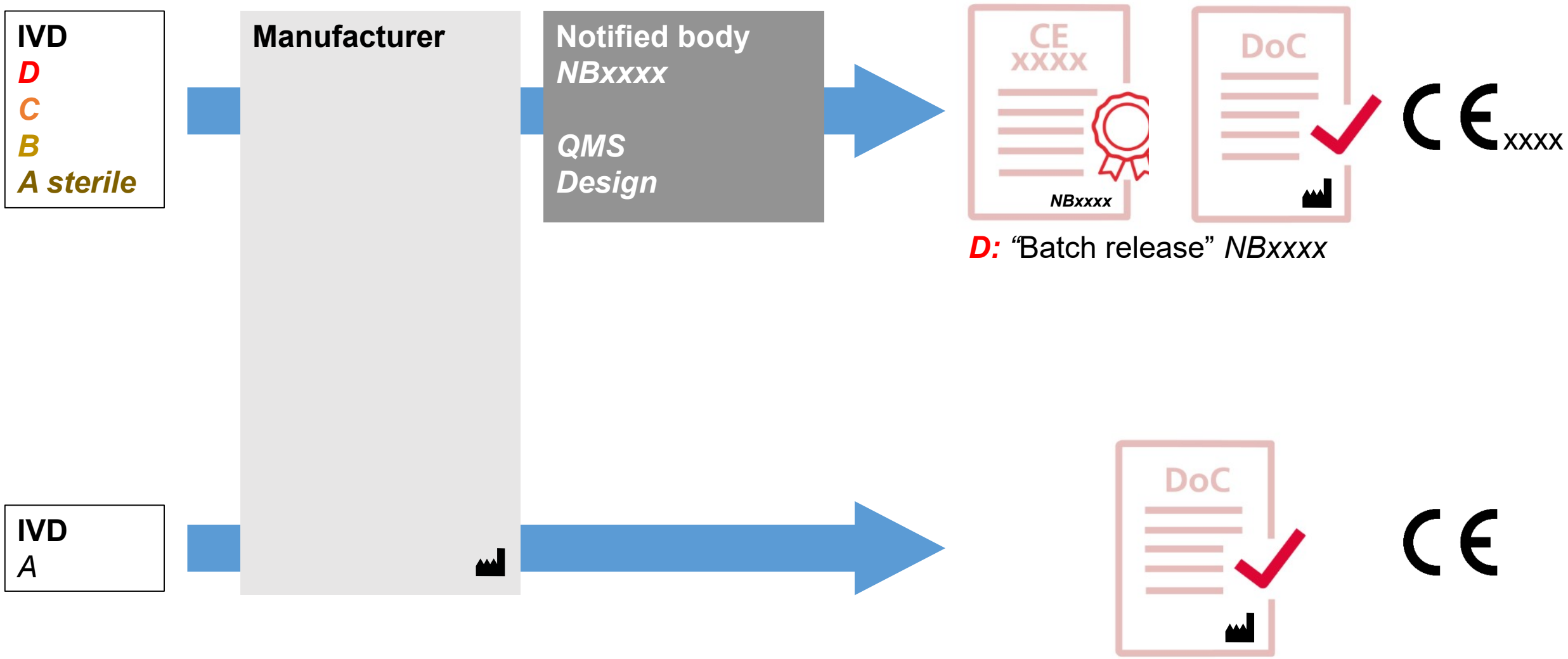
MDCG 2020-16 rev.1

Guidance on Classification Rules for *in vitro* Diagnostic Medical Devices under Regulation (EU) 2017/746

January 2022

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745.
The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

IVD
D
C
B
A sterile
A


IVD
D
C
B
A sterile
Manufacturer
Notified body
NBxxxx
QMS
Design
CE
xxxx
NBxxxx
DoC
CE xxxx
D: "Batch release" NBxxxx
IVD
A
DoC
CE

Quality management system

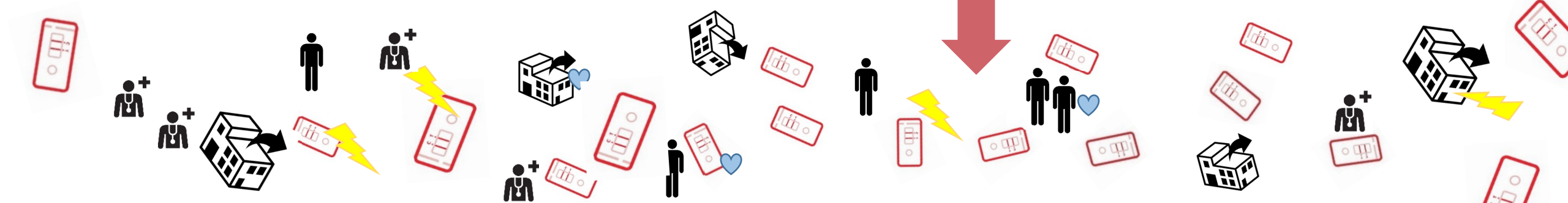
Design
Performance evaluation
Risk management
…

Post-market surveillance system

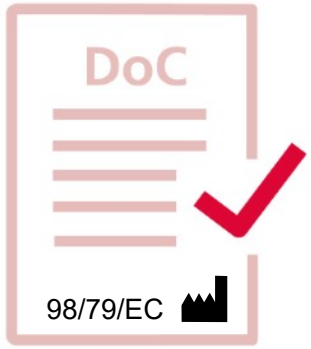
PMS plan

PMS report
A ***B*** - as required

PSUR
C ***D*** – 1 / yr



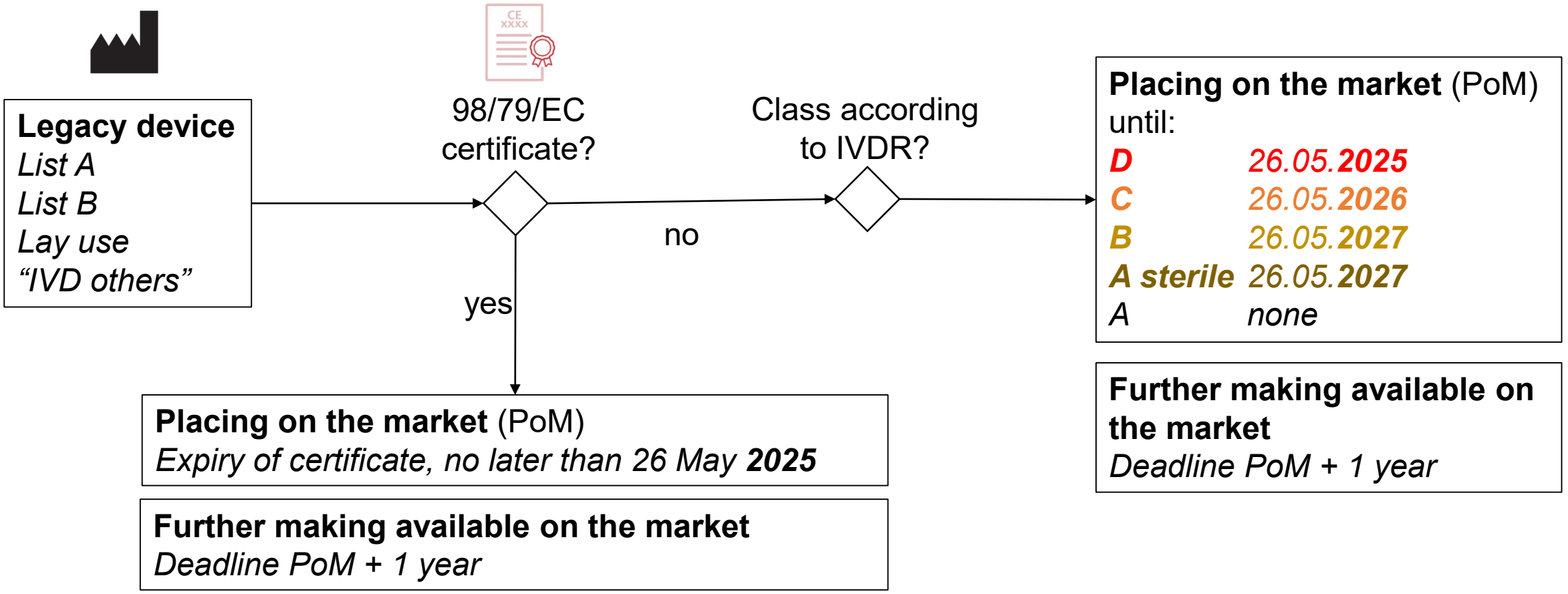
Legacy devices from 26 May 2022



Before
26 May 2022

Significant changes in design and intended purpose

As old legislation



Important: IVDs placed on the market in CH before 26 May 2022: Make available on the market until 26.05.**2025**

The **post-market surveillance**, […] **vigilance** [and] **registration** of economic operators and of the devices themselves are subject to the provisions of the IvDO.

Placing on the market of devices that comply with the old legislation, Art. 82 para. 2 IvDO

Concept new regulation

Classes *A*, ***B***, ***C***, ***D***

Conformity assessment

Post-market surveillance

Deadlines for legacy devices

IvDO MDCG IVDR SMC

Sources, references and information

Manufacturer's obligations

Definition: Art. 4 para. 1 let. e IvDO

Obligations: Art. 39-43 IvDO, Art. 10 IVDR

Assumption of manufacturer's obligations by third parties: Art. 16 paras. 1 and 2 IVDR

Notification to Swissmedic: IVD notification (swissmedic.ch)

General Safety and Performance Requirements (GSPR)

Art. 6 IvDO, Annex I IVDR

Designated standards: Art. 45 para. 4 TPA, information from Switec

Common specifications: Art. 45 para. 4 TPA, see relevant EU IVDR implementing regulations, currently Implementing Regulation (EU) 2022/1107

Performance evaluation

Art. 39 para. 3 IvDO, Art. 56 and Annex XIII IVDR

Clinical evidence: MDCG 2022-2

Software: MDCG 2020-1

Classification

Art. 14 IvDO, Annex VIII IVDR

Classification guidelines: MDCG 2020-16

Classification of software: MDCG 2019-11

Conformity assessment

Art. 17 and 19 IvDO, Art. 48 and Annexes IX-XI IVDR

Class D verification by NB: MDCG 2022-3

Post-market surveillance

System: Art. 49 and 50 IvDO, Art. 78 para. 3 IVDR

Post-market surveillance plan: Art. 51 IvDO, Annex III para. 1 IVDR

Post-market surveillance report (A&B): Art. 52 IvDO

Safety report (C&D): Art. 53-55 IvDO

Legacy devices: Transitional periods and manufacturers' obligations

Art. 81 -82 IvDO

Application of IVDR requirements to legacy devices: MDCG 2022-8

Significant changes: MDCG 2022-6

General questions: Frequently Asked Questions on medical devices (swissmedic.ch)

Note: This summary is for information purposes only and is not a complete summary of the relevant legal requirements.