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ANTWERP

BSAC/NVC congress

Implementation of the IVD Regulation

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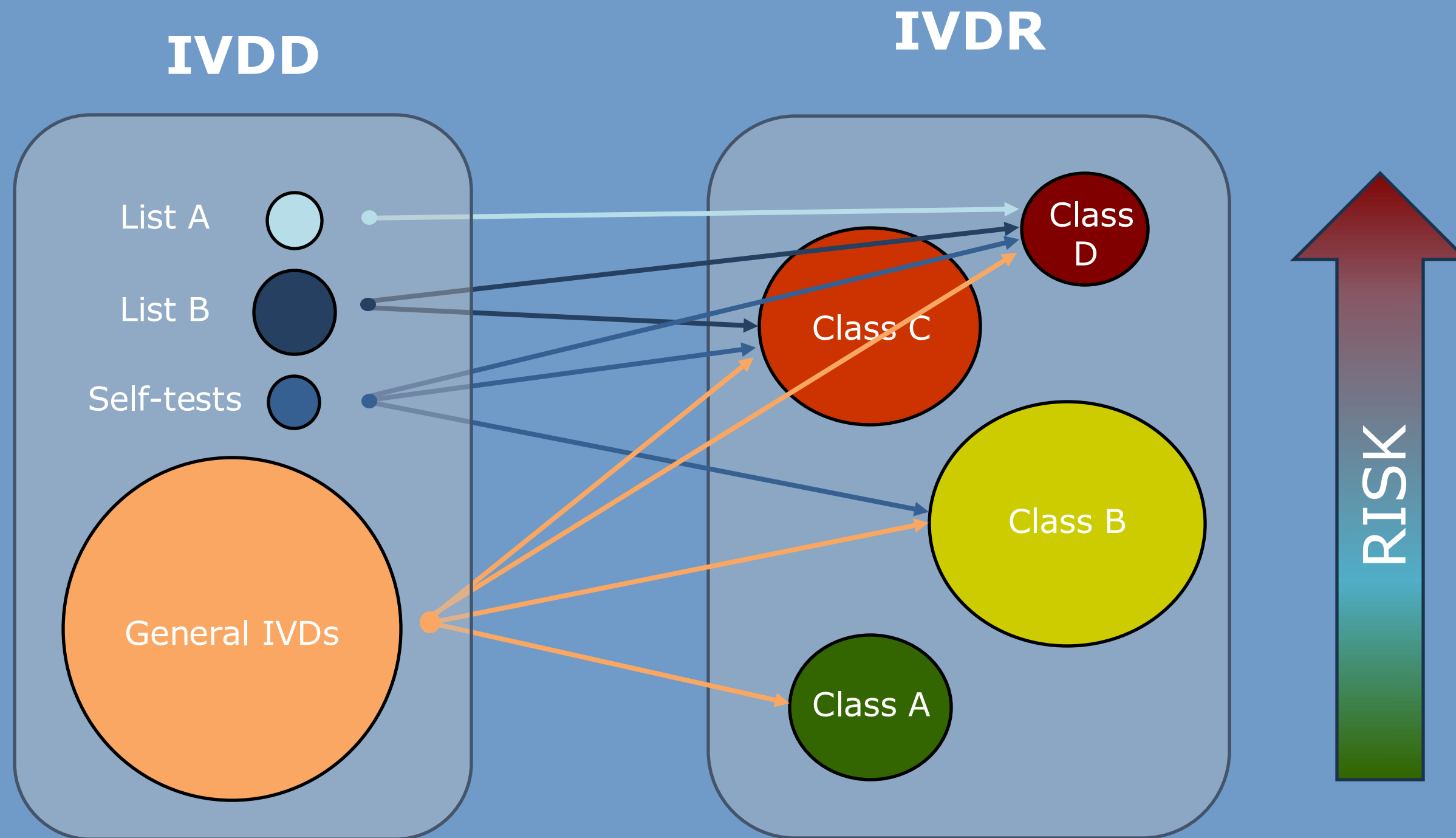
Some background on IVDR:



- IVD Regulation (IVDR) published in 2017
- Replaces the IVD Directive (IVDD) from 1998
- Goal: to increase quality, safety and performance, transparency
- Applicable since 26 May 2022
- Major changes: e.g. (1) classification, (2) more actors involved, focus on (3) performance and on (4) transparency

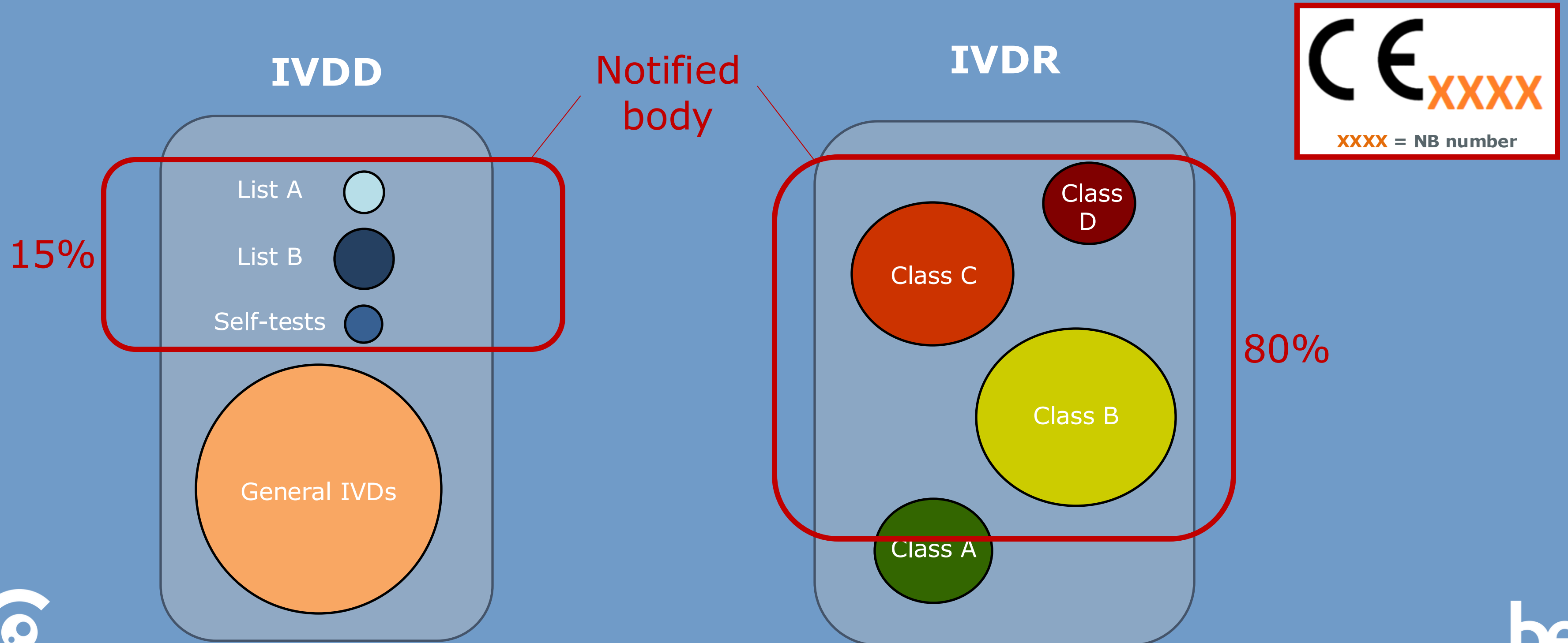


Major changes (1): classification



Major changes (2): actors involved

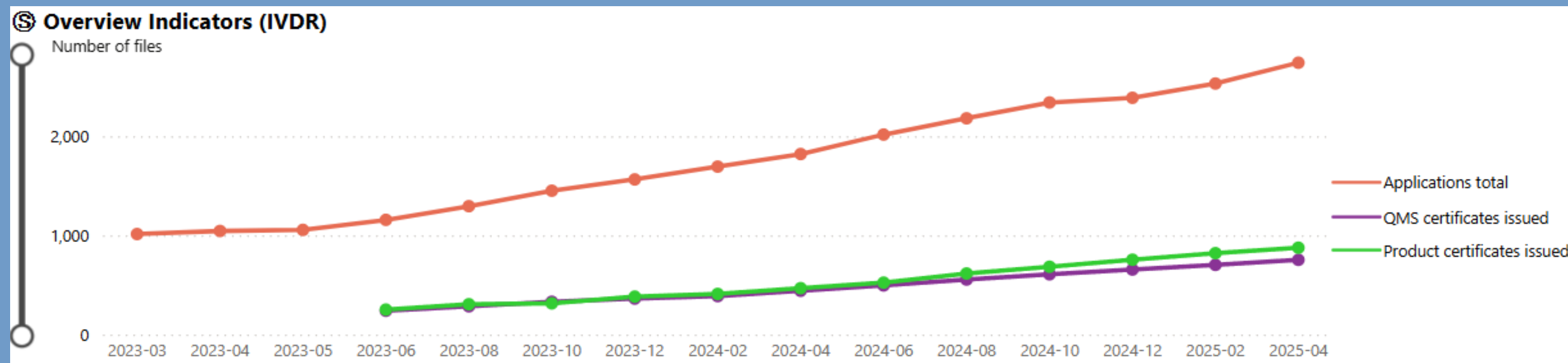
Notified Bodies (NBs)



Major changes (2): actors involved

Notified Bodies (NBs)

- Currently 19 NBs designated for the IVDR, one Belgian (SGS)
- NBs indicate sufficient capacity for new clients
- Steady increase in applications and issued certificates



Major changes (2): actors involved

EU reference laboratories (EURLs)

- EURL tasks:
 - premarket verification of the performance of class D IVDs
 - test samples/batches of manufactured class D IVDs
- At present, 6 categories of IVDs covered, i.e. detection/quantification of markers of:
 - 1) hepatitis or retrovirus infection (ISC, PEI)
 - 2) herpesvirus infection (CQS, ISC, SERMAS)
 - 3) infection with bacterial agents (CQS, ISC, SERMAS)
 - 4) respiratory virus infection (PEI, RISE)
 - 5) parasite infection (ISC, CQS)
 - 6) blood grouping (PEI, CQS, RISE)
- State of play after 1st wave of 2nd call:
 - Parasites (2) + blood grouping (3)
 - [Implementing act](#) 16 December 2025
 - Transition period for the 2 new scopes: 1 May 2026



Major changes (2): actors involved

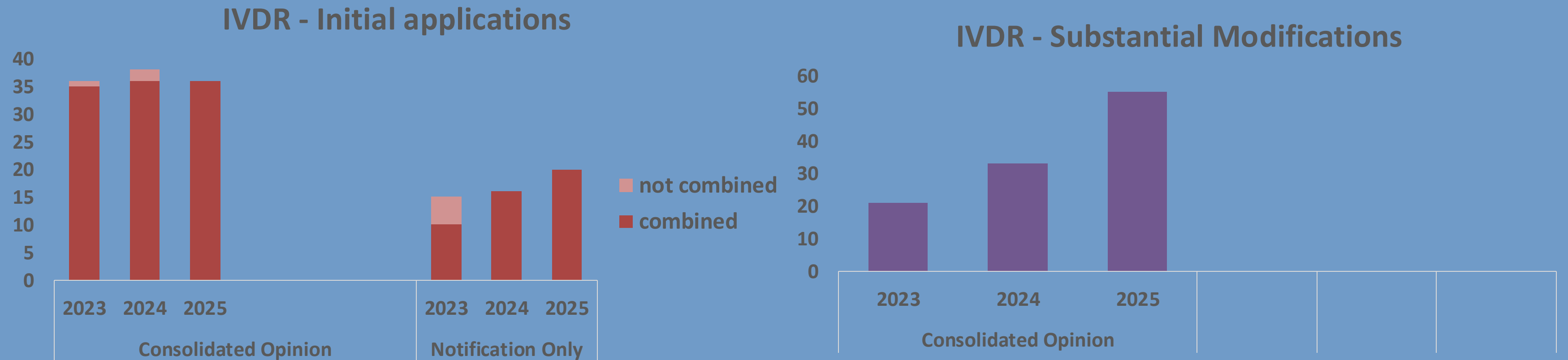
IVD expert panel

- Tasks: - review the performance evaluation for certain new class D IVDs
- scientific, technical or clinical advice, e.g. [advice on the down-classification](#) of SARS-CoV-2 tests from class D to class B in 2025
- Reviews of performance evaluations are [public](#)
- 22 members (1 from BE), but continuous open [call](#) from the European Commission (either for the IVD panel or for a central list of eligible candidates)



Major changes (3): focus on performance (studies)

- Authorisation required for high(er)-risk studies, e.g. interventional performance studies
- Number of applications submitted to FAMHP: graph 2023, 2024 and 2025



- Almost all those studies are combined: companion diagnostic – medicinal product

Implementation of IVDR article on in-house IVDs

- Health institutions wishing to develop and use in-house IVDs should follow provisions of Art. 5(5)
- Article 5(5): subsections (a) to (i) are applicable since 26/05/2024, except for subsection (d) on equivalent CE marked IVDs (applicable from 31/12/2030)
- In-house IVDs must meet the General Safety and Performance Requirements (GSPR) of Annex I
- [Public declaration](#) from health institutions containing the in-house IVDs and stating their compliance with GSPR



Implementation of article 5(5)

- Public declaration: automatically rendered via FAMHP's web portal

The screenshot shows the FAMHP web portal with several sections highlighted by blue boxes and annotated with grey callout boxes. The top navigation bar includes language options (NL, FR, EN), a Help link, a Logout button, and the .be logo. The main header features the text 'Federal Agency for Medicines and Health Products' and the 'famhp' logo.

My alerts (blue box)

My activities (blue box) - Application gathering the different activities of the company

My devices (blue box) - Applications intended for notifications :
- of devices distributed by the company.
- of custom devices manufactured by the company
- for health institutions: in-house devices and reprocessed devices

My company (blue box) - Application gathering:
- Company details
- Data that will be used in other applications

My controls (blue box) - Application with all the information related to the inspections:
- Risk analysis form
- Status of an inspection
- Communication platform between the inspector and the inspected

My Free sale certificates (blue box) - Not for in-house

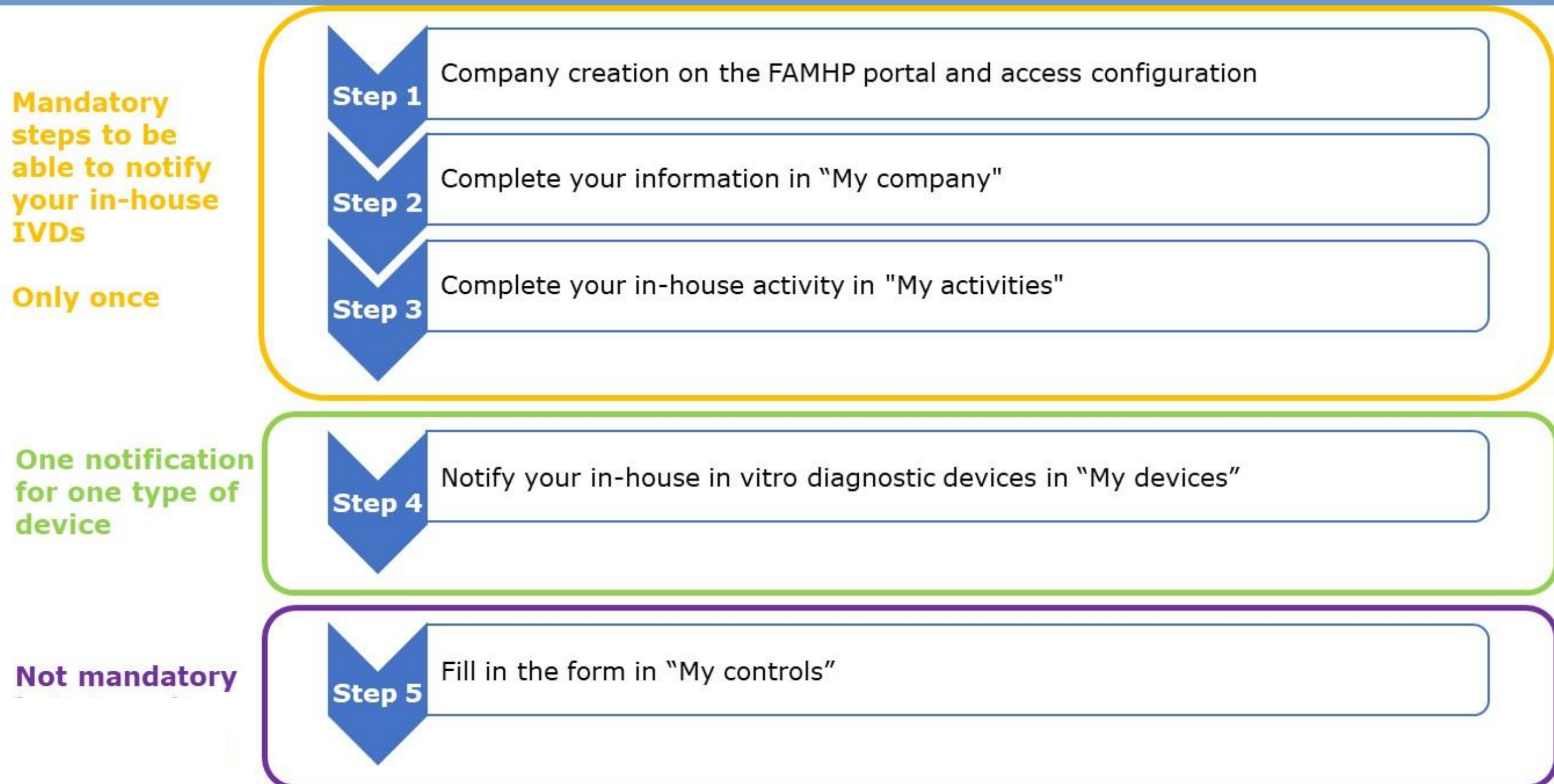
My Contributions (blue box) - Not for in-house

Other visible elements include 'Manage my activities', 'My distributed/manufactured devices', 'My notifications of manufacturing and reprocessing', 'Name of the company', 'Adress of the company', 'VAT number: BEXXXXXXXXXX', 'FAMHP number: BE/CA01/1-YYYYY', 'Manage my company details', 'Manufacturer', 'Fill in my form', 'My dossier', 'Authorized representative', 'Fill in my form', and 'My dossier'.



Implementation of article 5(5)

- Steps to register in-house IVDs in the web portal



Implementation of article 5(5)

- **Changes** to existing CE marked IVDs
 - Practical approach followed: only significant changes in intended use or design will yield an in-house IVD (see [Q&A document](#), also available in [FR/NL](#))
- **Inspections** (inspection.meddev@fagg-afmps.be)
 - Take into account reports from Sciensano/BELAC
- **Performance studies** (CT.RD@fagg-afmps.be)
 - Authorisation only needed for high-risk studies (e.g. interventional study). See [guideline](#) for the application of a performance study.
- **Vigilance** (vigilance.meddev@fagg-afmps.be)
 - Which incidents should be reported? See decision tree ([FR/NL](#))
 - To whom? Either directly to FAMHP or via the contact point materiovigilance in hospital
 - How? Via form ([FR/NL](#))
- Definition of **legal entity and health institution**
 - See practical interpretation in BE ([FR/NL](#))
 - Upcoming revision of the EU guidance on in-house devices



Proposal IVDR revision

Why?

- Reduce administrative burden
- Enhance predictability and cost-efficiency of notified bodies' certification processes
- Conformity assessments more proportionate to IVD risk-class

What?

Many articles will be revised: focus **Article 5(5)**

- Transfer allowed in specific cases
- CE marked equivalency provision removed
- ISO15189 compliance OR GSPR
- ...
- Market access for some IVDs will be stimulated: breakthrough devices + orphan devices



Where to find further information?

- FAMHP's [webpage on in-house IVDs](#) :
 - FAMHP's [web portal](#) for registering in-house IVDs
 - User guide to register your health institution and your activity ([FR/NL](#))
 - User guides to register your IVDs:
 - notification by notification ([FR/NL](#))
 - [by group of notification](#)
 - instructions ([FR/NL](#))
 - [Webinar](#) on the full procedure
 - [European guidance on in-house devices](#)
 - [Q&A document](#) (also available in [FR/NL](#))
- [European guidance on IVD classification](#)



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