IVDR Regulatory Updates – 18 months after the DOA

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28 November 2023

Agenda

- IVDR Timelines since original DOA
- Regulatory Updates EU MDR and IVDR
- IVDR Status Quo at Notified Bodies
- IVDR moving forth from here
- Q&A Session

Agenda

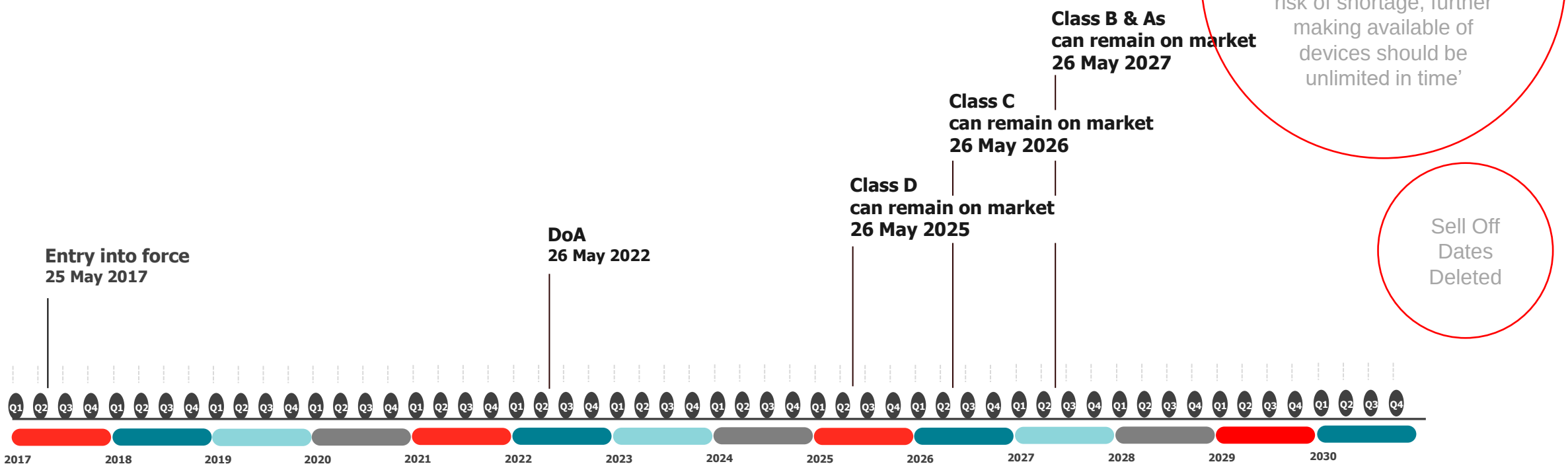
- IVDR Timelines since original DOA

- Poll #1

IVDR Timelines since original DOA

- At the moment, we are 18 months into the IVDR after the original Date of Application (26 May 2022)
- Big relief has been seen after publication of Regulation (EU) 2022/112 (transitional provisions)
- In the meantime, notified bodies (a.o. BSI) have been very busy dealing with the applications that were sent in from manufacturers
- This road to compliance has been quite “rocky” to say the least, leading to a steep learning curve for both manufactures as well as notified bodies
- Currently, applications inflow seems to go to a “steady state”

IVDR Timelines since original DOA



'to prevent unnecessary disposal of safe MD & IVD that are still in the supply chain, thus adding to the imminent risk of shortage, further making available of devices should be unlimited in time'

Sell Off Dates Deleted

Agenda

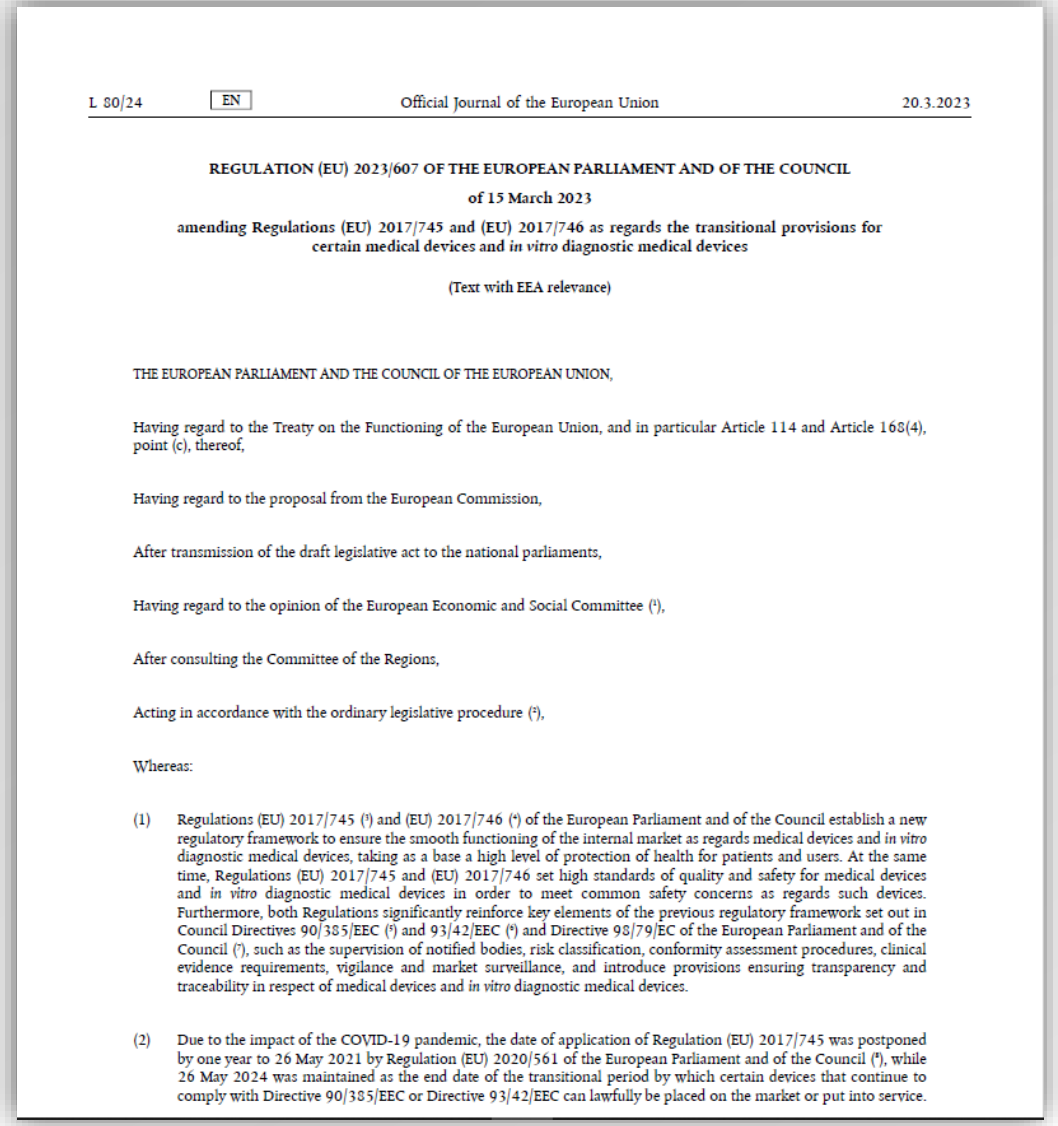
- Regulatory Updates EU IVDR and MDR

Regulatory Updates EU IVDR and MDR

- Most important (recent) updates in EU MD Regulations are the result of
  - The (lack of) preparedness for the regulations by different stakeholders (manufacturers, competent authorities, notified bodies) and regulatory unclarity on the interpretation of the requirements.
  - Regulatory unclarity of the requirements of the IVDR and MDR (clinical, PMS, market surveillance, introduction of other regulations, AI)
  - Preparedness of EUDAMED
  - Large volume of MDR and IVDR applications from manufacturers
- A call to action (industry organizations) was initiated towards the EU Commission to address this (EPSCO meeting December 2022)
- This resulted in the publication of the EU Regulation 2023/607 (March 15, 2023)

Most important themes resulting from 2023/607

- The need for the amending regulation
- Scope & timelines of the extension of the MDR transitional period
- Conditions to be met for benefitting from the extended transition timelines
- Appropriate surveillance to be performed by Notified Bodies
- Other important considerations for manufacturers (MDR readiness)
- Abolishment of the sell-off dates (IVDR)



L 80/24 EN Official Journal of the European Union 20.3.2023

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Regulations (EU) 2017/745 (3) and (EU) 2017/746 (4) of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC (5) and 93/42/EEC (6) and Directive 98/79/EC of the European Parliament and of the Council (7), such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council (8), while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

Poll #2

How to deter the imminent risk of shortage of medical devices?

Extend the validity of MDD/AIMDD certificates,

Extend the transitional period

(for legacy devices transitioning to MDR or substitute devices subject to certain conditions)

AND

Abolish the sell-off provisions in MDR and IVDR – Devices once placed on the market under the Directives can be further made available and put into service for unlimited time

(5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The extension should be of sufficient duration to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.

(6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.

(10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available on the market or putting into service of devices which are placed on the market by the end of the applicable transitional period and which are still in the supply chain one year after the end of that transitional period. To prevent the unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of such devices, such further making available on the market or putting into service of such devices should be unlimited in time.

? Do devices already certified under MDR benefit from the extended validity of the corresponding directive certificates? **Yes, if all the applicable conditions are met**

Regulatory Updates EU IVDR – Implementing and Delegated acts

- Commission Implementing Regulation (EU) 2022/944 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of in vitro diagnostic medical devices.
  - ➢ This affects the to be designated EU Reference Laboratories; limited impact on IVD manufacturers.
- Commission Implementing Regulation (EU) 2022/945 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and the Council with regard to fees that may be levied by EU reference laboratories in the field of in vitro diagnostic medical devices.
  - ➢ This affects the to be designated EU Reference Laboratories; no impact on IVD manufacturers.
- Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council.
  - ➢ This affects the Class D IVD devices; big impact for Class D IVD manufacturers.
- Commission Delegated Regulation (EU) 2023/503 of 1 December 2022 amending Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies.
  - ➢ This affects competent authorities and notified bodies; no impact on IVD manufacturers.

Regulatory Updates EU IVDR – MDCG Guidance documents

Reference	Title	Publication Date
MDCG 2020-16	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	02/2023
MDCG 2022-17	MDCG position paper on "hybrid audits"	12/2022
MDCG 2022-15	Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD	09/2022
MDCG 2022-19	Performance study application/notification documents under Regulation (EU) 2017/746	12/2022
MDCG 2022-20	Substantial modification of performance study under Regulation (EU) 2017/746	12/2022
MDCG 2021-22	Clarification on “first certification for that type of device” and corresponding procedures to be followed by notified bodies, in context of the **consultation of the expert panel** referred to in Article 48(6) of Regulation (EU) 2017/746	09/2022
MDCG 2023-4	Medical Device Software (MDSW) – Hardware combinations Guidance on MDSW intended to work in combination with hardware or hardware components	10/2023
Manual on Borderline	Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 – Version 2	09/2023

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Regulatory Updates EU IVDR – TEAM-NB Updates

Reference	Title	Publication Date
https://www.team-nb.org/wp-content/uploads/members/M2023/Team-NB%20PositionPaper-BPG-IVDR-V1-20230225.docx	TEAM-NB Position Paper – BPG for the submission of Technical Documentation against IVDR (EU) 2017/746	25/02/2023
https://www.team-nb.org/wp-content/uploads/members/M2023/Team-NB-PositionPaper-HybridAudits-V2-20230516.docx	Notified bodies' paper on the application of hybrid audits to quality management system assessments under MDR/IVDR	16/05/2023
https://www.team-nb.org/wp-content/uploads/members/M2022/Team-NB-PositionPaper-ModificationsSamplingPlan-V1.docx	TEAM-NB Position Paper on Modifications Sampling Plan	08/12/2022
https://www.team-nb.org/wp-content/uploads/members/M2022/Team-NB-PositionPaper-IVDR-Significant%20changes-V1.docx	TEAM-NB Position Paper on IVDR Significant Changes	08/12/2022
https://www.team-nb.org/wp-content/uploads/2022/10/Team-NB-PositionPaper-InterimmeasuresVerifclassD-V1-20221005.pdf	TEAM-NB Position Paper Interim Measures Verification Class D	05/10/2022
https://www.team-nb.org/wp-content/uploads/2023/08/Team-NB-PositionPaper-TransferAgreement-V1-20230811-1.pdf	Transfer Agreement – specifying the terms of voluntary change of notified body under Regulation (EU) 2017/745 or (EU) 2017/746	05/10/2022
	TEAM-NB Press Release!: Call for submitting IVDR Applications; https://www.team-nb.org/wp-content/uploads/2023/10/Team-NB-PressRelease-Capacity-NotifiedBodies-during-transition-IVDR-MDR-October2023.pdf	

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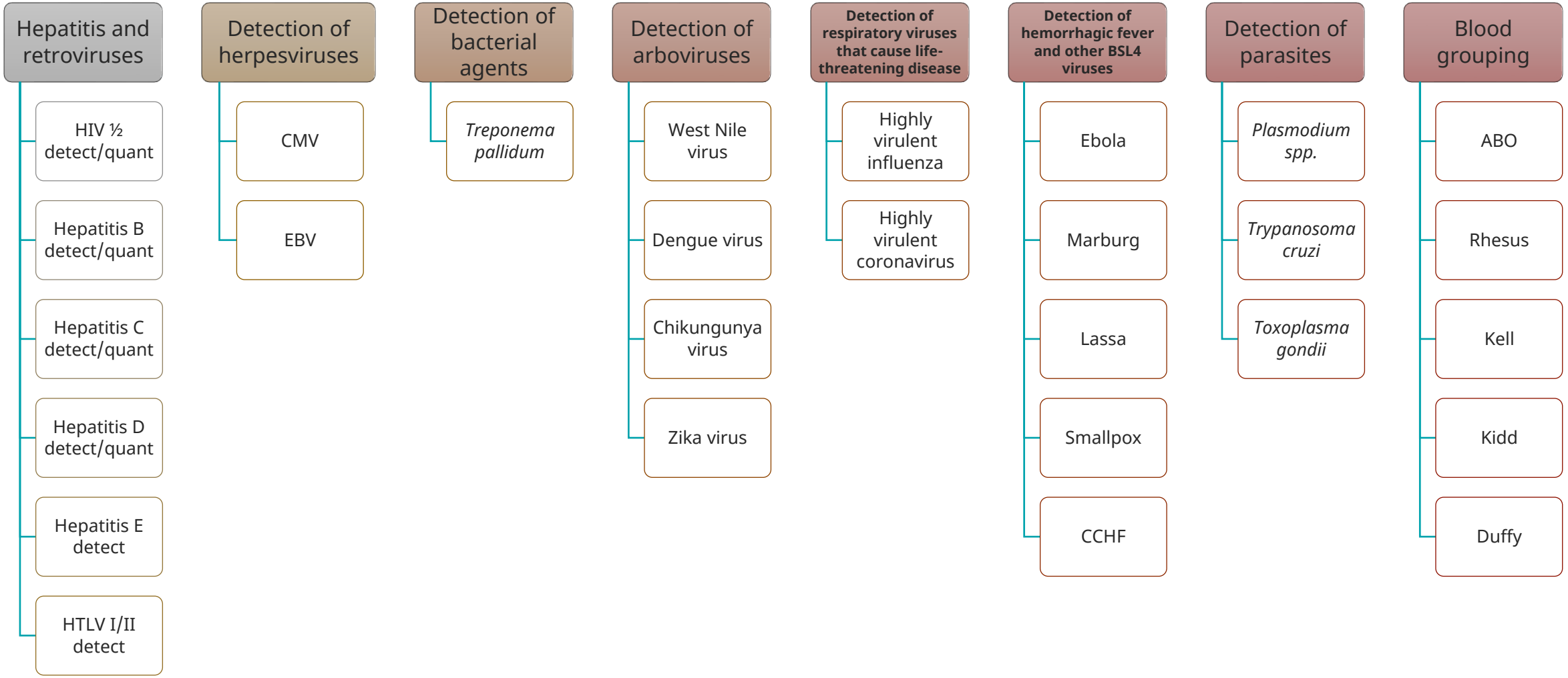
Class D and EURL situation

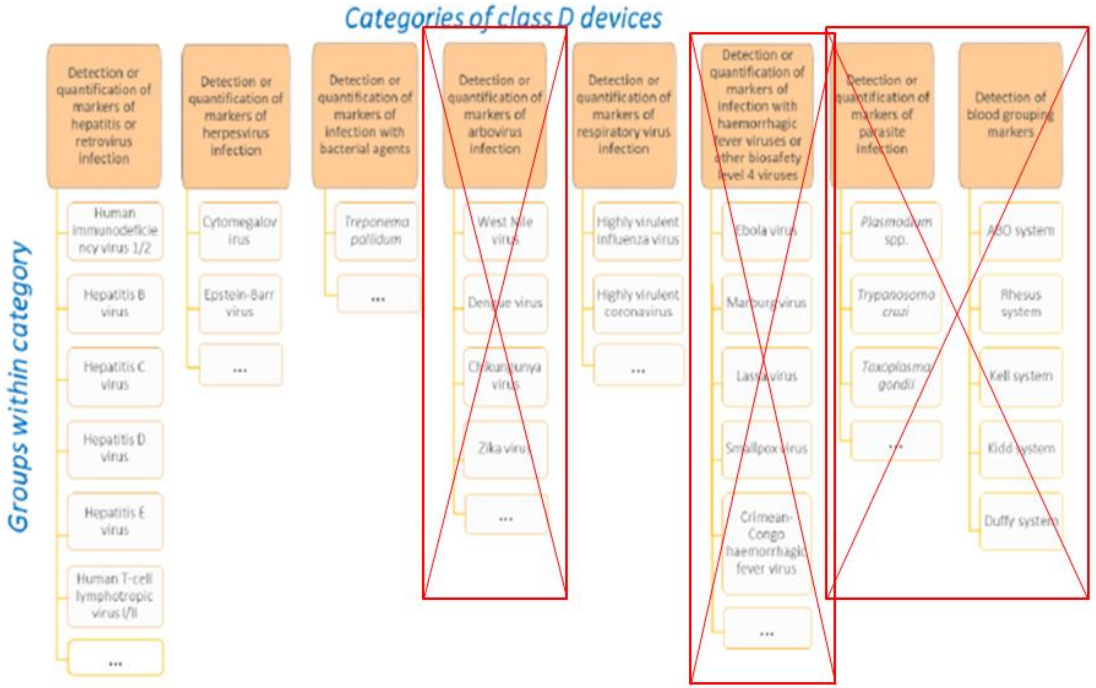
- Initial call launched in July 2022 finding EURLs for 8 categories
- Time constraints for call: getting EURLs asap vs allowing them enough time to prepare candidature
- Jan 2023 deadline for laboratories to apply to Member States -> evaluation
- 31 Mar 2023 deadline for the MS to submit to EU COM
- EU COM analyses capacity and verified MS assessment
- Designation act planned for ~~Q3~~ Q4 2023

EURL scopes of designation in call (original)



Class D and EURL situation

- A total of 5 EURLs are to be designated covering 4 areas (meaning half of them are not covered)
- Implementing act drafted and to be finalised, expected by November
- EURLs areas that are not covered: arboviruses, hemorrhagic fever and other biosafety level 4 viruses, parasites and blood grouping (!?)
- Designation expected for
  - Hepatitis and retroviruses
  - Herpesviruses
  - Bacterial agents
  - Respiratory viruses that cause life-threatening diseases
- Designation expected ~~Q3~~/Q4 2023
- Transition period: currently it is mentioned 9 months, most probably 12 months after publication



Class D and EURL situation

- Legacy devices are not subject to EURL testing: this refers to IVDD devices, so batch testing is carried out as required by the IVDD. EURL concept does not exist under the IVDD.
- For third party testing activities under the IVDR: can go on until the designation for the task until the end of the transition period.
- An EURL cannot start before the transition period has ended (gun-start); method harmonization needs to happen between EURLs.
- EURLs can outsource work to another EURL when testing activities is within the scope. Testing should be planned in advance.
- Timing of performance verification activities is still a bit of debate…
- BSI will continue with the existing process and make preparations for working together with EURLs in the near future, once they become designated…
- IVD Notified Bodies will need to look at alternative measures for remaining technical areas…

Agenda

- IVDR Status Quo at Notified Bodies

Poll #3

IVDR Status Quo

- Number of IVDR Notified Bodies that have been designated is 12, whereas another 11 CAB organizations have applied (in the queue), CAPA plans have been approved…
- In the meantime, until June 2023 a total of 500 IVDR certificates have been issued by all IVDR Notified Bodies altogether
- Number of IVDR applications received seems to have gone down as of Q3 2022 but is now picking up again.
- As a result, more capacity has been freed up that enables Notified Bodies to carry out conformity assessments in a more predictable manner, also leading to shorter review periods
- Notified Bodies will prioritize device reviews, based on Classification and application date per IVDR:
  - Class D: **26 May 2025**
  - Class C: **26 May 2026**
  - Class B and Class A sterile: **26 May 2027**
- **Call to action** has been sent out to manufacturers to submit their Class D applications by Q1 2024

IVDR Notified Bodies – current status

IVDD Notified Bodies, n=19

Search results (19)

NOTIFICATION STATUS Active

LEGISLATION 98/79/EC In vitro diagnostic medical devices

Body type	Body Name	Country
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0318	CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS	Spain
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Italy
NB 0459	GMED SAS	France
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0537	Eurofins Electric & Electronics Finland Oy	Finland
NB 0543	Presafe Denmark A/S	Denmark
NB 1011	NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Korlátolt Felelősségű Társaság (NEOEMKI LLC)	Hungary
NB 1023	INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s. (INSTITUTE FOR TESTING AND CERTIFICATION) merged with ex-NB 1390	Czech Republic
NB 1293	EVPU a.s.	Slovakia
NB 1434	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.	Poland
NB 2265	3EC International a.s.	Slovakia
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2854	bqs. s.r.o.	Slovakia
NB 2934	CeCert Sp. z o.o.	Poland

IVDR Notified Bodies, n=12

Search results (12)

NOTIFICATION STATUS Active

LEGISLATION Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Body type	Body Name	Country
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0459	GMED SAS	France
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0537	Eurofins Electric & Electronics Finland Oy	Finland
NB 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2962	QMD Services GmbH	Austria
NB 3018	Sertio Oy	Finland

source: Nando (22nd November 2023)

IVDR Notified Body Capacity (status October 2022 ➡ June 2023)

Notified Bodies Survey on certifications and applications (MDR/IVDR)

Survey results with data status 30 June 2023
(medium and small dataset)

25 October 2023

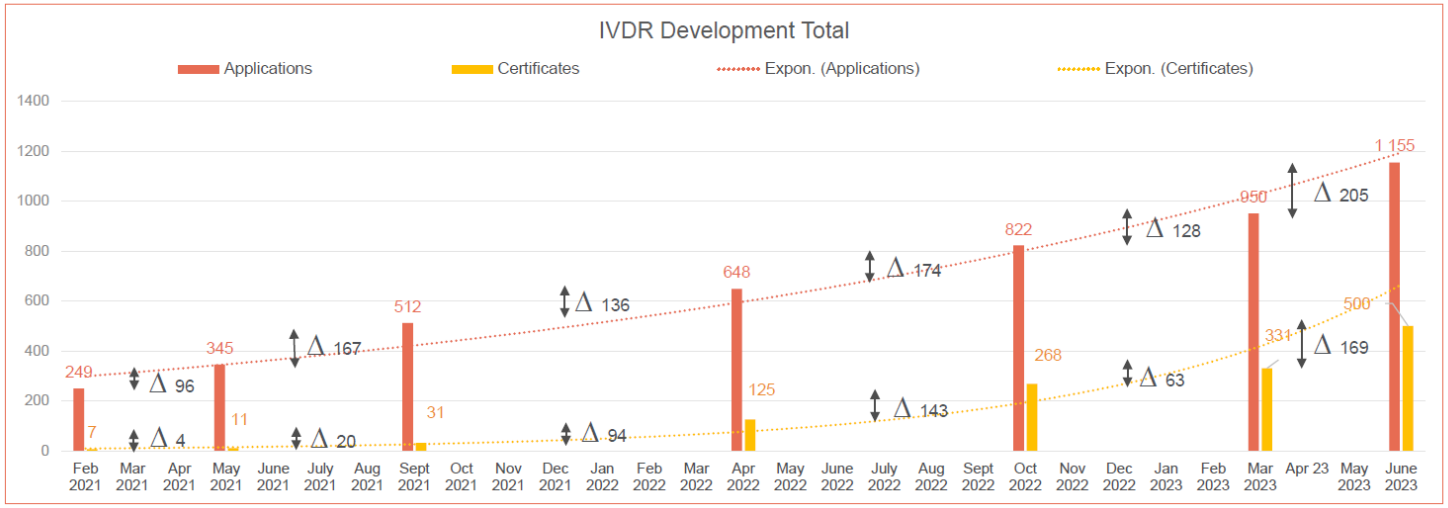
1

IVDR applications lodged and certificates issued

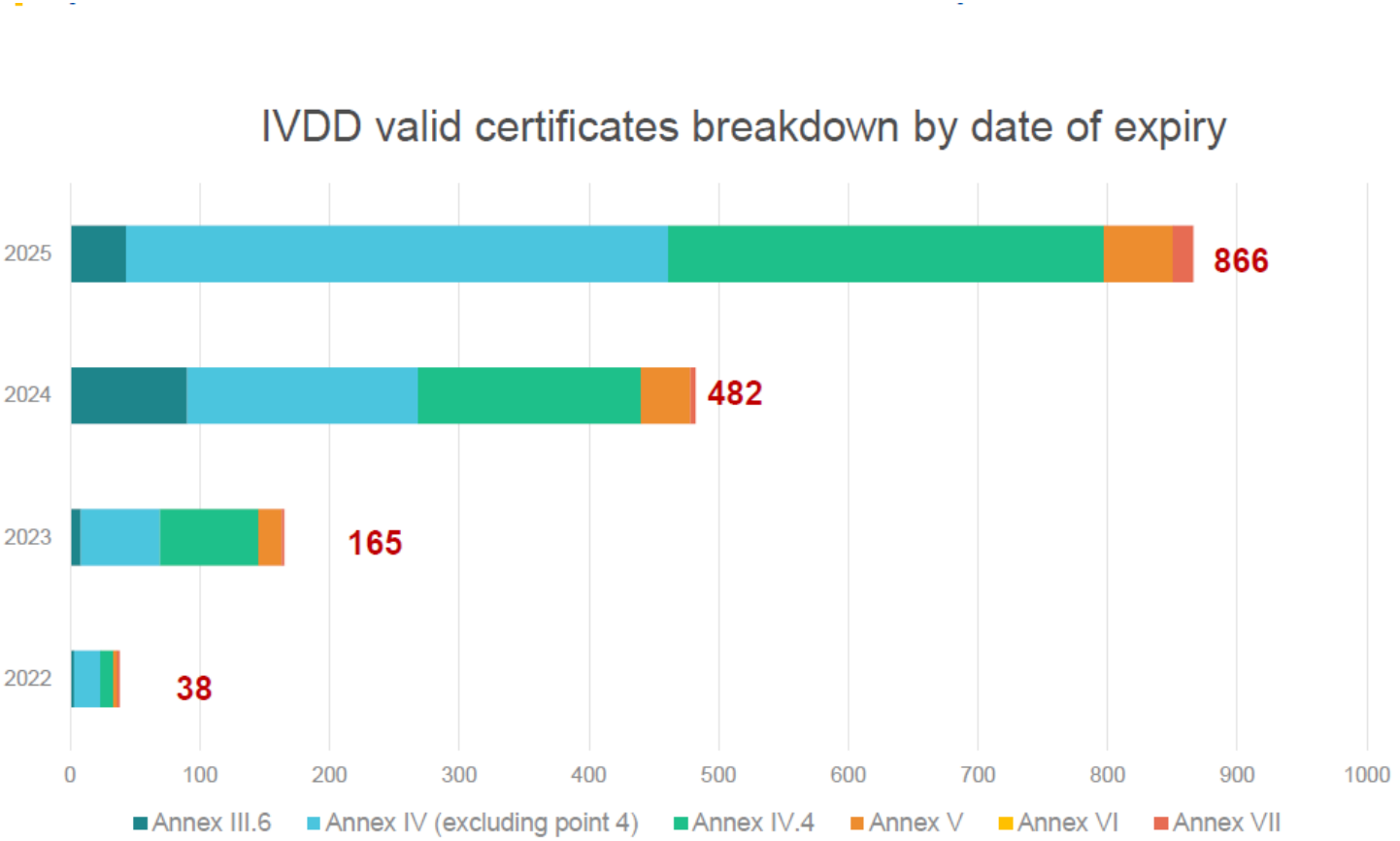
IVD

Medium dataset

June 2023
IVDR Applications: 1.155
IVDR Certificates: 500



IVDR Status Quo: EC Survey results 30th June 2023 - IVDD



IVDD Data
Data from survey of October 2022
(20 out of 21 replies received from NB designated under IVDD)

Tot. valid IVDD certificates 1.551

*Notified Bodies Survey on certifications and applications(MDR/IVDR)
Survey results with data status 30 June 2023 (medium and small dataset)
6 October 2023 (Preview version)

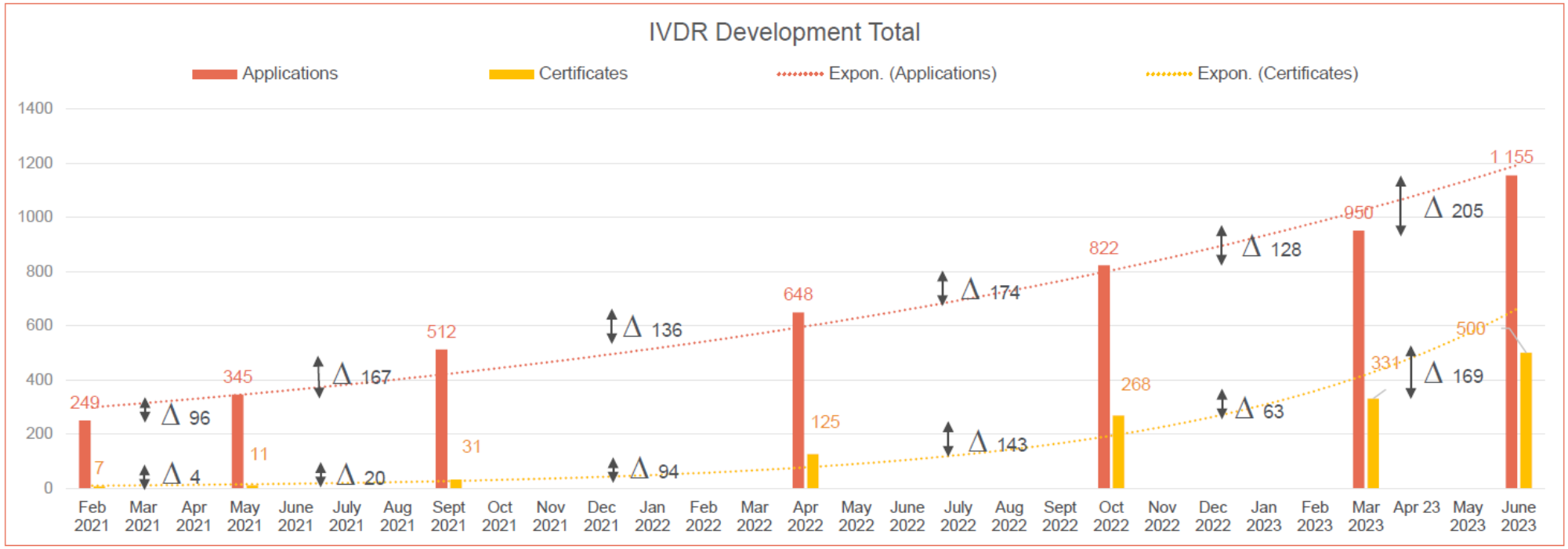
IVDR Status Quo: EC Survey results 30th June 2023 - IVDR

IVDR applications lodged and certificates issued

IVD

Medium dataset

June 2023
IVDR Applications: 1.155
IVDR Certificates: 500



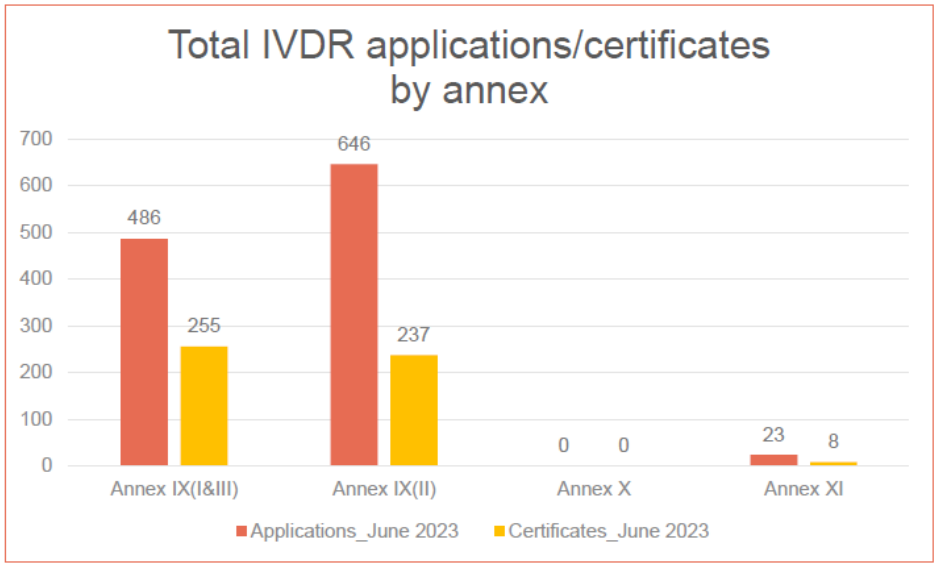
Total March to June delta:

Certificates: 331 (M.) versus 500 (J.):Δ 169

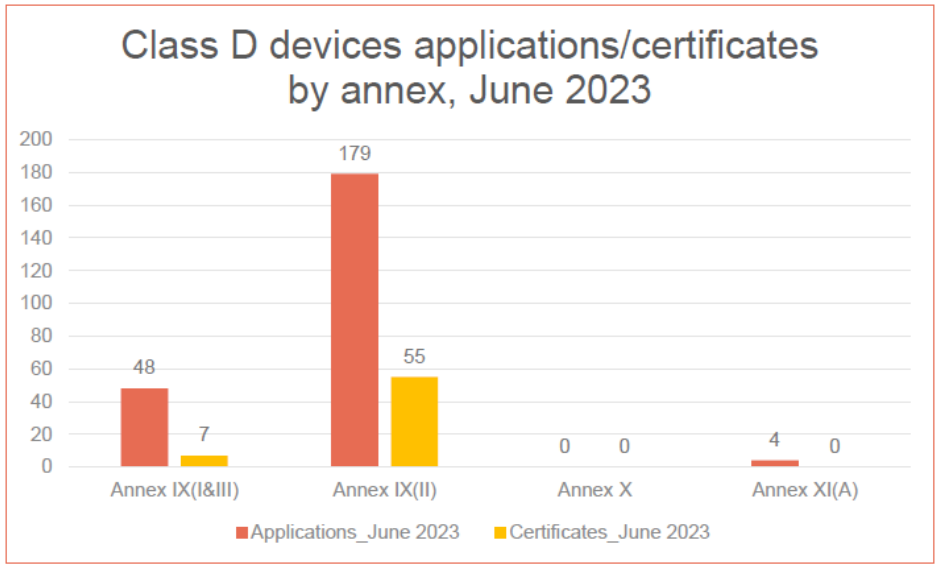
Applications: 955 (M.) versus 1155 (J.) Δ 205

IVDR Status Quo: EC Survey results 30th June 2023 - IVDR

IVDR certificates and applications - June 2023



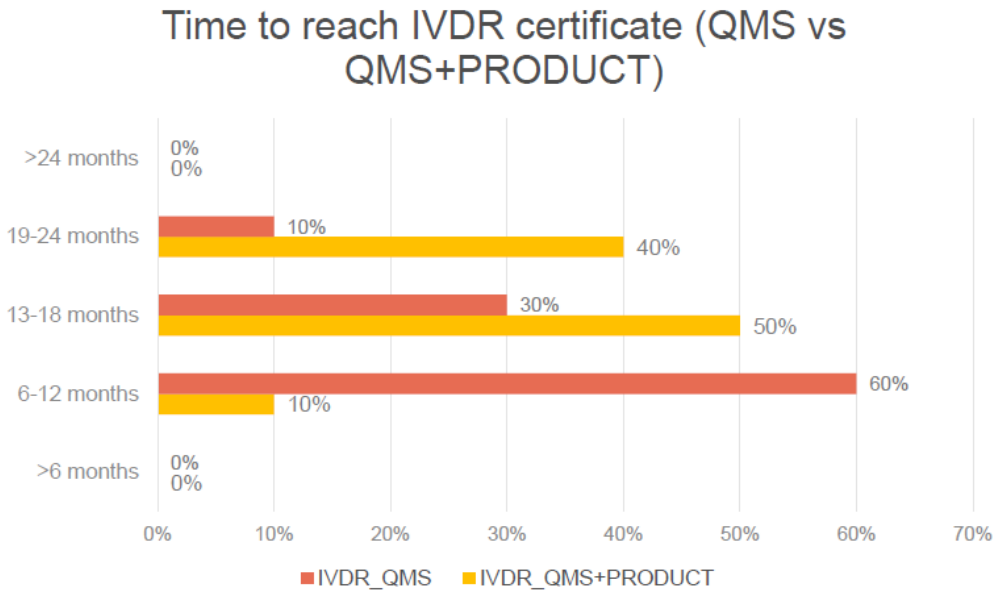
June 2023
IVDR Applications: 1.155
IVDR Certificates: 500



June 2023:
Class D devices Applications: 231
Class D devices Certificates: 62

*Notified Bodies Survey on certifications and applications(MDR/IVDR)
Survey results with data status 30 June 2023 (medium and small dataset)
6 October 2023 (Preview version)

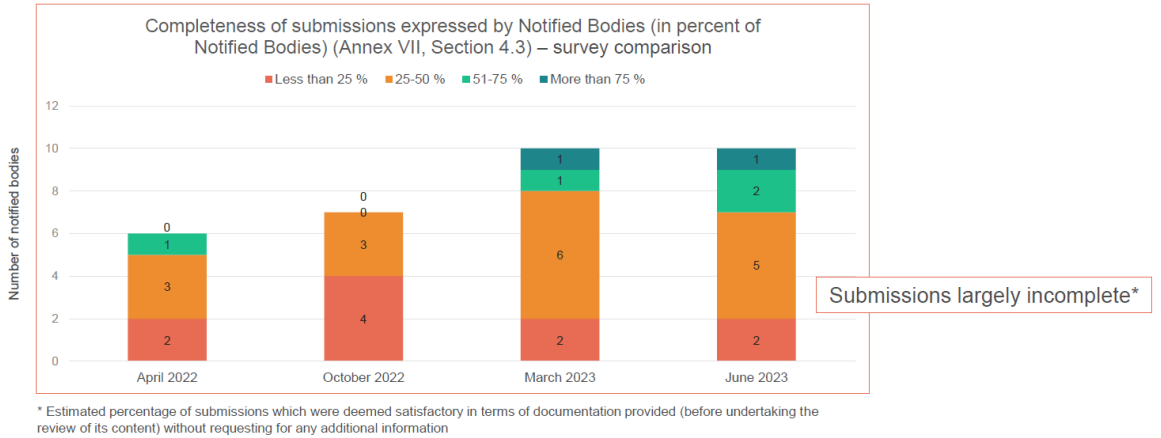
IVDR Status Quo: EC Survey results 30th June 2023 - IVDR



Completeness of submissions

IVD

Medium dataset



Submissions largely incomplete*

* Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

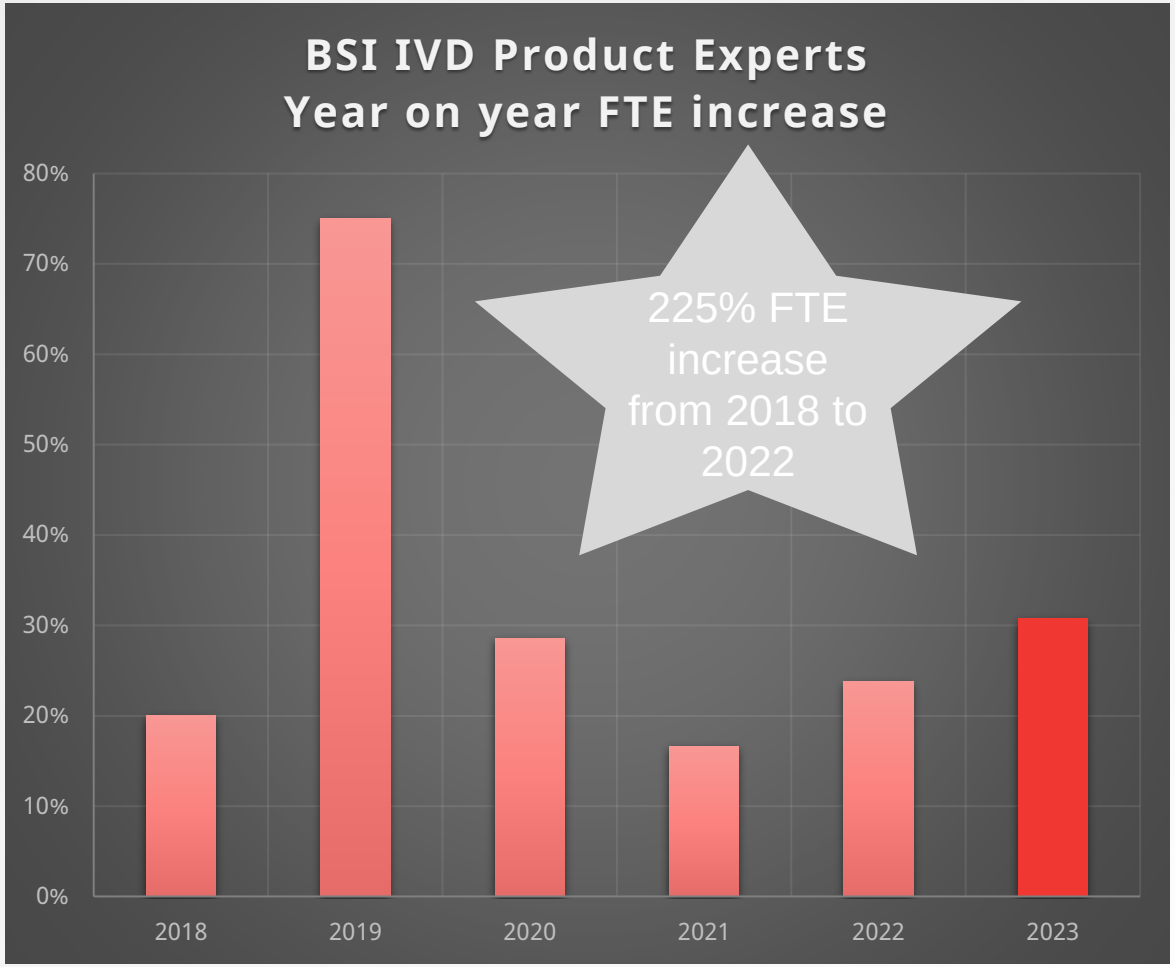
*Notified Bodies Survey on certifications and applications(MDR/IVDR)
Survey results with data status 30 June 2023 (medium and small dataset)
6 October 2023 (Preview version)

Agenda

- IVDR moving forth from here

IVDR Notified Body Journey BSI

BSI IVDR journey	
2010	IVDD designation
2014	First IVDR product expert hire
2017	IVDR Entry into force
Dec 2019	IVDR designation
Jun 2020	IVDR applications ramp up
Dec 2020	First BSI IVDR certificate issued
Jan 2022	IVDR transition change published
May 2022	IVDR Date of Application
Jan 2023	First BSI Class D certificates issued
May 2023	First BSI CDx certificates issued



IVDR moving forth from here: What are the challenges for the NB?

- IVDR applications are coming in, while at the same time, surveillance and oversight activities related to devices already certified under IVDR must be undertaken by Notified Bodies; PSUR review for Class D, SSP validations, Surveillance Assessments, etc.
- Class D scrutiny procedure has not been fully applied in accordance with the IVDR, without the designation of the EU Reference Labs => Alternative measures are sought and implemented by the Notified Bodies.
- 26 May 2025 is the first real date to watch: Class D devices will need to meet IVDR requirements, while at the same time, CE certificates of legacy IVD's that have been certified under the IVDD will expire (Annex II List A, Annex II List B and Self-tests).
- Companion Diagnostics conformity assessment is very much a learning curve for both Notified Bodies as well as the EMA.
- Across the board, Notified Bodies do still have limited capacity; only 10 IVDR Notified Bodies have been designated.

IVDR moving forth from here: Is there a problem for the IVDR NB's?

It depends…for the moment, IVDR Notified Bodies are getting momentum in their certification process, leading to more IVDR certificates in relatively quicker fashion, compared to 2021 and 2022.

- Amount of IVDR Notified Bodies have expanded from 6 in early 2022 to 10 in January 2023.
- Applications are processed more quickly; seems to be more consistency among Notified Bodies.

But…

- Amount of new IVDR applications have dropped in 2023, compared to 2021/2022; +/-30%
- Some IVD manufacturers have withdrawn the IVDR applications, to come back "at a later date".
- This is not a good development, since it is expected that another wave of applications will come in 2024 (when?)….

IVDR moving forth from here…

- IVDR implementation has been a “**rocky road**”, as already made clear.
- IVDR Notified Bodies are now working towards a new “**steady state**”, where technical dossiers are assessed more consistently; lead times are still very much depended on the quality of the documentation provided…
- As stated, EC are now conducting **surveys** with Notified Bodies, competent authorities and manufacturers to monitor the implementation and determine “road-blocks”, if we were just be able to use EUDAMED for this…
- Focus of EC is to make implementation of the regulations as “**effective as possible**”; also, focus on implementation of MDCG 2022-14.
- Obviously, it takes “two” to tango, or in the case of Europe; **three**. On the short term, for IVDR, Joint Implementation rollout is followed. On the medium term, new priorities are defined:
  - Orphan IVD’s
  - COMBINE project: IVDR/MDR/CTR alignment

IVDR moving forth from here…

Biggest IVDR priorities for the coming year(s):

- IVDR Notified Bodies will **prioritize conformity assessments** for devices, based on IVDR Class, where possible.
- **EURLs** will be designated in Q4 2023, but the implementation will require quite some effort on the side of the Notified Bodies and manufacturers to make this work.
- New **Common Specifications** are expected to be approved and published in Q1 2024; this will also help in clarifying the requirements for Class D IVD's.
- Updating MDCG 2021-14 (IVDR codes) and revision of NBOG 2014-3 on significant changes
- Awaiting publication of revision MDCG 2022-9 (SSP template)
- Impact of **Expert Panel** advice
- Harmonization of some IVD specific standards (e.g. ISO 18113)
- Further in the future; rethink the governance process in relation to MDR and IVDR (>3 years).

Key take aways…

- After a **rocky start**, the IVDR implementation by NBs seems to have taken off
- In the period between 2021 and 2023, a total of **500** IVDR CE Certificates have been issued (status June 2023)
- Biggest **challenge** for the short term remains certification of Class D IVD’s
- After years of uncertainty, the designation of EURLs seem to be **finally happening**
- Designation of EURLs will happen with a transition period, not all technical areas are going to be covered
- IVDR Notified Bodies will therefore stick to rolling out **alternative means** for these areas
- In the upcoming period, IVDR Notified Bodies will **prioritise and plan** dossier reviews per classification due date

Q&A

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