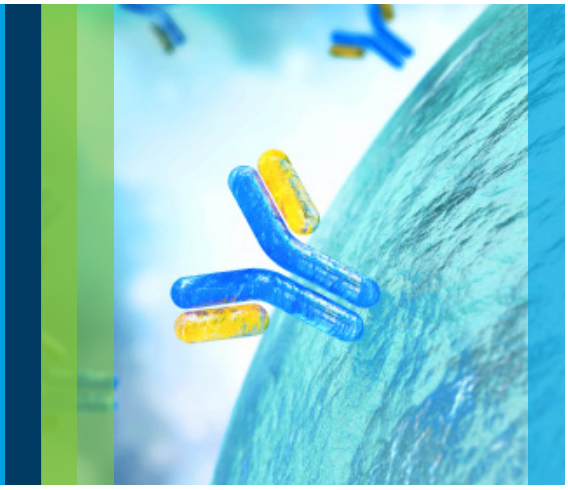
Supporting Clinical Labs with **New** EU IVDR Regulation



Key Dates

- For devices that were not certified or self-certified under IVDD prior to 26 May 2022, the deadline was 26 May 2022.
- For devices that were certified or self-certified under IVDD prior to 26 May 2022, the progressive rollout deadlines are as follows:

  Class A - 26 May 2022
  Class B - December 2029
  Class C - December 2028
  Class D - December 2027

Agilent is committed to meeting the new EU IVDR 2017/746 requirements and amending transitional provisions on time.

Citing a desire for improved patient safety and significant technological advances in recent years, the European Commission (EC) replaced the In Vitro Diagnostic Directive (IVDD) with a new, harmonized regulatory framework: the In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746.

Devices that were not certified or self-certified under IVDD prior to 26 May 2022 came under IVDR regulation as of 26 May 2022. Additionally, the EC and the European Parliament have adopted a progressive rollout of the IVDR regulation, establishing new transitional periods (that extend into the year 2029) according to device risk classes.

At Agilent, we recognize that the new IVDR framework has a significant impact on your diagnostic laboratory. As a manufacturer of in vitro diagnostic (IVD) products, we are able support you and your clinical lab through this regulatory transition.

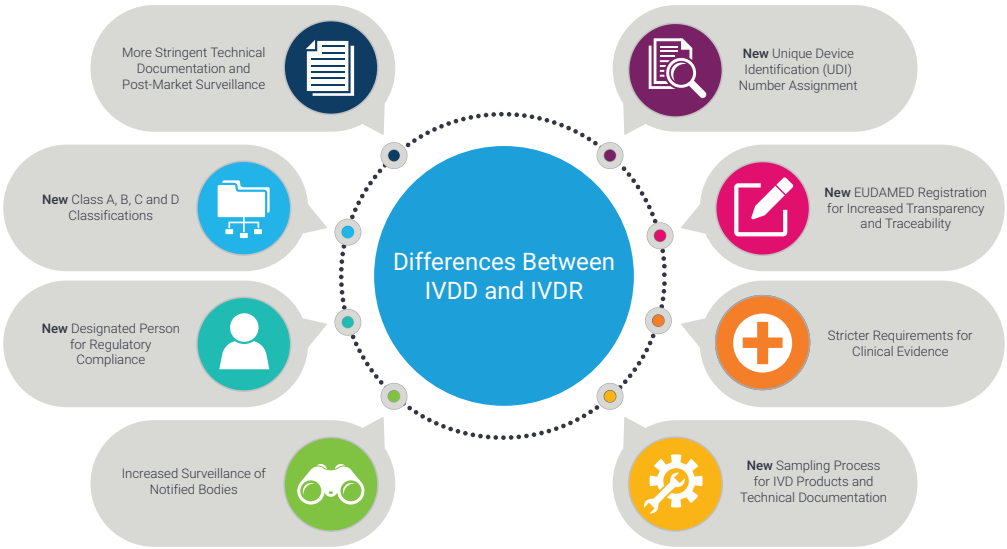


Figure 1. Differences between IVDD and IVDR. Key changes include clinical evidence requirements, pre-market review of technical files by a Notified Body, post-market surveillance and vigilance, transparency and traceability through UDIs and strengthening of the oversight of the IVDs by the Notified Body.

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Trusted Answers

Genomics

- Microarrays
- Next generation sequencing
- qPCR

Anatomic Pathology

- Immunohistochemistry
- H&E
- Special Stains
- FISH
- CDx

Flow Cytometry & Specific Proteins

- Flow cytometry
- Nephelometry
- Turbidimetry
- ELISA

Figure 2. Our IVDR Product Portfolio. At Agilent, we offer diagnostic products that fall under three main product categories, Genomics, Anatomic Pathology and Flow Cytometry & Specific Proteins. Regardless of which products you use from us, we are committed to the highest standards of quality for all of our products and services.

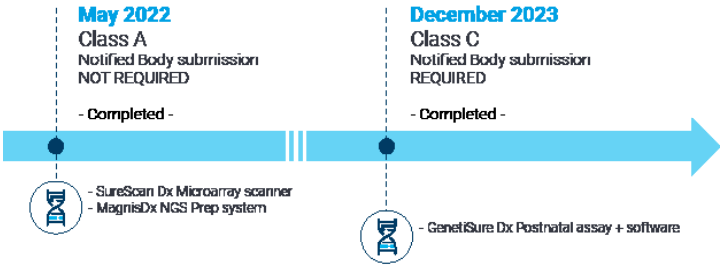

Figure 3. Genomics Product Portfolio Timeline for IVDR Certification. Shown are the Genomics products that are IVDR compliant.

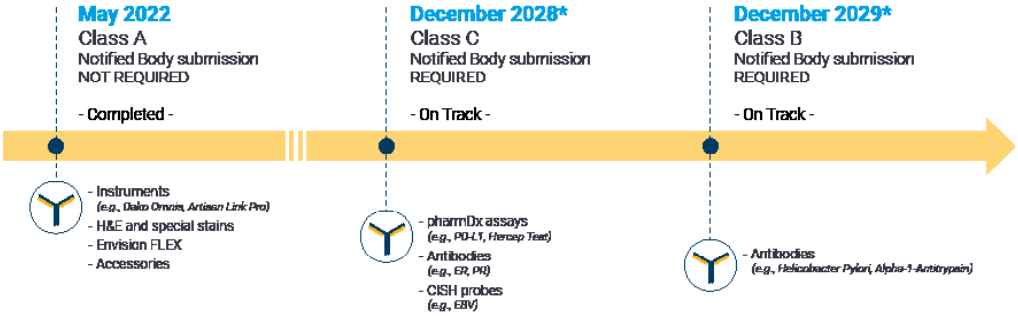

Figure 4. Anatomic Pathology Product Portfolio Timeline for IVDR Certification. Shown are the Anatomic Pathology products that are IVDR compliant as of May 26, 2022 and those products that will be IVDR compliant in the future (The Class C and B products mentioned fall under the progressive roll-out timeframe for existing on-market CE-IVD products and have a new IVDR deadline of December 2028 and 2029, respectively).

**Note that the compliance deadline applies to existing on-market CE-IVD products. Products placed into market on/after May 26, 2022, must be IVDR-compliant. No Class D products available at this moment.*

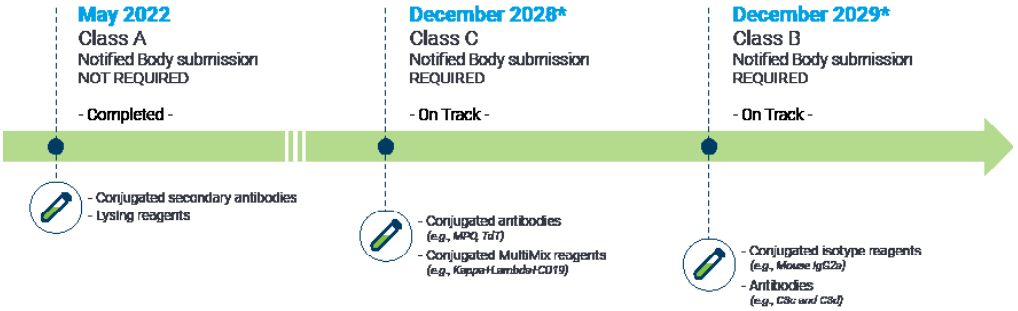

Figure 5. Flow Cytometry and Specific Proteins Product Portfolio Timeline for IVDR Certification. Shown are the Flow Cytometry and Specific Proteins products that are IVDR compliant as of May 26, 2022 and those products that will be IVDR compliant in the future (The Class C and B products mentioned fall under the progressive roll-out timeframe for existing on-market CE-IVD products and have a new IVDR deadline of December 2028 and 2029, respectively).

**Note that the compliance deadline applies to existing on-market CE-IVD products. Products placed into market on/after May 26, 2022, must be IVDR-compliant. No Class D products available at this moment.*

CE 0123
IVD

The GenetiSure Dx Postnatal assay hold IVDR Class C certificaiton in Europe.

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For in vitro diagnostic use.
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This information is subject to change without notice.

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