MedTech Europe
from diagnosis to cure

EU IVDR/MDR Implementation Quarterly update from MedTech Europe

MedTech Europe Webinar

21 February 2022

Welcome to Europe!

Today's Agenda

1. **Welcome** - *Merlin Rietschel*
2. **IVDR amendment to extend the transitional provisions (link)** - *Petra Zoellner* – 15 min
3. **MDR - state of play** - *Jana Moravcova* – 5 min
4. **International Affairs** – *Diana Kanecka* - 10 min
   - Update on EU IVDR impact on international registration
   - Update on Certificate of Free Sales

Remember

- There will be Q&A session at the end
- Feel free to leave your questions in the chat

IVD Regulation (IVDR)

IVD Regulation – extended transitional provisions

Publication of amending Regulation (EU) 2022/112 – in a nutshell

Gives 3-5 years extended transitional periods to *most* IVDD devices

Keeps 26 May 2022 deadline for instruments and other lowest-risk IVDs

Saves *existing* tests, not innovations

~~Gives 2-6 years transition for most lab-developed tests' requirements~~

Publication of amending Regulation (EU) 2022/112 - details

1. The 26 May 2022 date of application is unchanged

- **Class A non-sterile** – including instruments! – need IVDR CE-marking to be placed on market from 26 May 2022
- **New devices** will need IVDR CE-marking to be placed on market from 26 May 2022

2. Transitional periods are extended to all existing tests that need Notified Body review under the IVDR

- Future Class D + IVDD Annex II: until 26 May 2025, *(+ sell-off period +1 year)*
- Future Class C: until 26 May 2026, *(+ sell-off period +1 year)*
- Class B, plus sterile Class A: until 26 May 2027 *(+ sell-off period +1 year)*

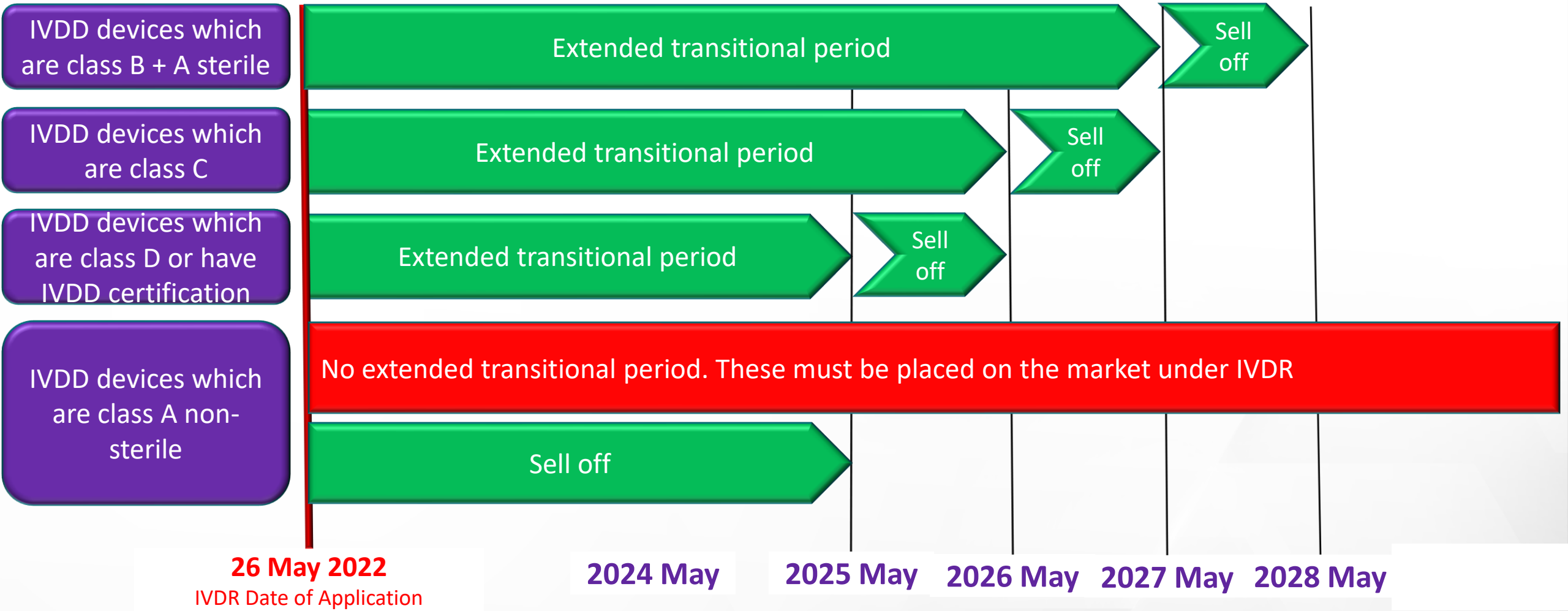
CONDITIONS for use of extended transitional periods for IVDD devices:

1. Before Date of Application: have EC Declaration of Conformity

2. After Date Application:

- Continue to comply with the IVD Directive
- No significant changes in device design and intended purpose
- Follow certain IVDR rules on post-market surveillance, vigilance and market surveillance, registration of economic operators and of devices

Amended transitional provisions for IVD Directive devices



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Some considerations for manufacturers

From now until 26 May 2022

For class A non-sterile:

- Make sure it has IVDR CE-marking if you want to place product on the market after 26 May 2022
- There is a sell-off period until 26 May 2025 for class A non-sterile which entered the supply chain *before* 26 May 2022

For legacy devices*:

- An EC Declaration of Conformity must already exist or be drawn up under the IVDD before 26 May 2022
- IF you have IVDD Notified Body certificates, consider if/how to extend them to 26 May 2025 – your Notified Body needs to do that before 26 May 2022!

**IVDD devices which will go to market under the IVDR extended transitional periods = "Legacy devices"*

Your Quality Management System will need to be updated

- For legacy devices: assign IVDR risk class, e.g.:
  - IVDD COVID-19 PCR test becomes class D under IVD Regulation = transitional period until 26 May 2025
  - IVDD cancer tests becomes class C under IVD Regulation = transitional period until 26 May 2026
  - IVDD urine test for glucose becomes Class B under IVD Regulation = transitional period until 26 May 2027
  - IVDD blood tubes become class A sterile under IVD Regulation = transitional period until 26 May 2027

- For legacy devices: incorporate as relevant the IVD Regulation requirements for PMS, vigilance, market surveillance, registration of actors and devices

- For all devices: track which products are 'legacy devices' or 'IVD Regulation devices'

Lots of EU guidance for legacy devices is on its way!

Legacy devices can have no significant changes in device design and intended purpose

- What is a significant change?

Legacy devices must comply with certain IVDR rules on post-market surveillance, vigilance and market surveillance, registration of economic operators and of devices

- What are the *exact* legal requirements which apply for legacy devices and their economic actors?
  - For example, do legacy devices need PSUR or Post-market surveillance report?

MDCG Guidance (mostly still) coming for IVD legacy devices

	PMS	Vigilance	Market surveillance	Actor/device registration	Significant changes to design/intended purpose
General guidance	• MDCG 2021-25 MDR requirements for MD legacy devices *(Adaptation for IVDR in Q2 2022)* • (MDCG 2021-1 Rev.1 fulfil EUDAMED requirements before EUDAMED is fully available) *(Adaptation for IVDR in Q2 2022)* • MDCG 2022-4 on appropriate surveillance by Notified Bodies for legacy devices				MDCG 2020-3 MDR significant changes *(Adaptation for IVDR in Q1 2022)*
Specific guidance				MDCG 2019-5 Registration of legacy devices in EUDAMED Also see: MDCG 2021-27 and MDCG 2021-26 importers and distributors	
Other	Coming soon! Update to European Commission Fact Sheet for Authorities in non-EU/EEA States on MD and IVD. It will explain extended transitional periods.				

Text in blue-grey indicates the available MDCG guidance is MDR-only

Thinking about when to do your certification? Here is some food for thought

- **There are just 6 Notified Bodies under IVDR – resources continue to be limited**
  - Until 26 May 2022, Notified Bodies will be busy with IVD Directive certifications (renewals, extensions and substantial changes). They also have already-scheduled work to complete for IVDR
  - If you do not have a Notified Body today: some manufacturers may delay conformity assessment due to extended transitional periods – this may open up access to a Notified Body
  - If you have manufacturing sites outside of EU: factor in time for onsite audits
  - If you choose to certify towards end of transitional periods – beware of certification bottlenecks!!

- **3-year transitional period for class D devices – it should not be considered as 'long'**
  - Lots of uncertainty over length of certification process, what happens when EU Reference Laboratories arrive, etc.

- **Amendment to the IVDR does *not* support any device which needs IVDR certification after 26 May 2022**
  - If you expect to have devices with 'unanticipated' significant changes, consider getting at least your EU QMS certification as soon as you have access to a Notified Body

MD Regulation (MDR)

Recently published MDCG guidance

Economic operators & legacy devices

1. MDCG 2021- 23: Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

2. MDCG 2021-26 Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

3. MDCG 2021-27 Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

4. MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

Classification

MDCG 2021-24 Guidance on classification of medical devices

Pending: guidance on Borderline with medicinal products – concerns regarding definitions

International Affairs

International registrations – EU MDR/IVDR impact?

- CE marking is used to support product registrations outside Europe
- EU MDR/IVDR will drive changes to certificates of free sale and product regulatory documentation
    - changes to regulatory documentation because of the EU MDR/ IVDR are likely to vary from product to product

- Most **changes deriving from the EU MDR/IVDR** will simply **mean that additional information is available** for existing devices i.e., **not expected to impact the use, effectiveness, performance or safety profile of the devices**.

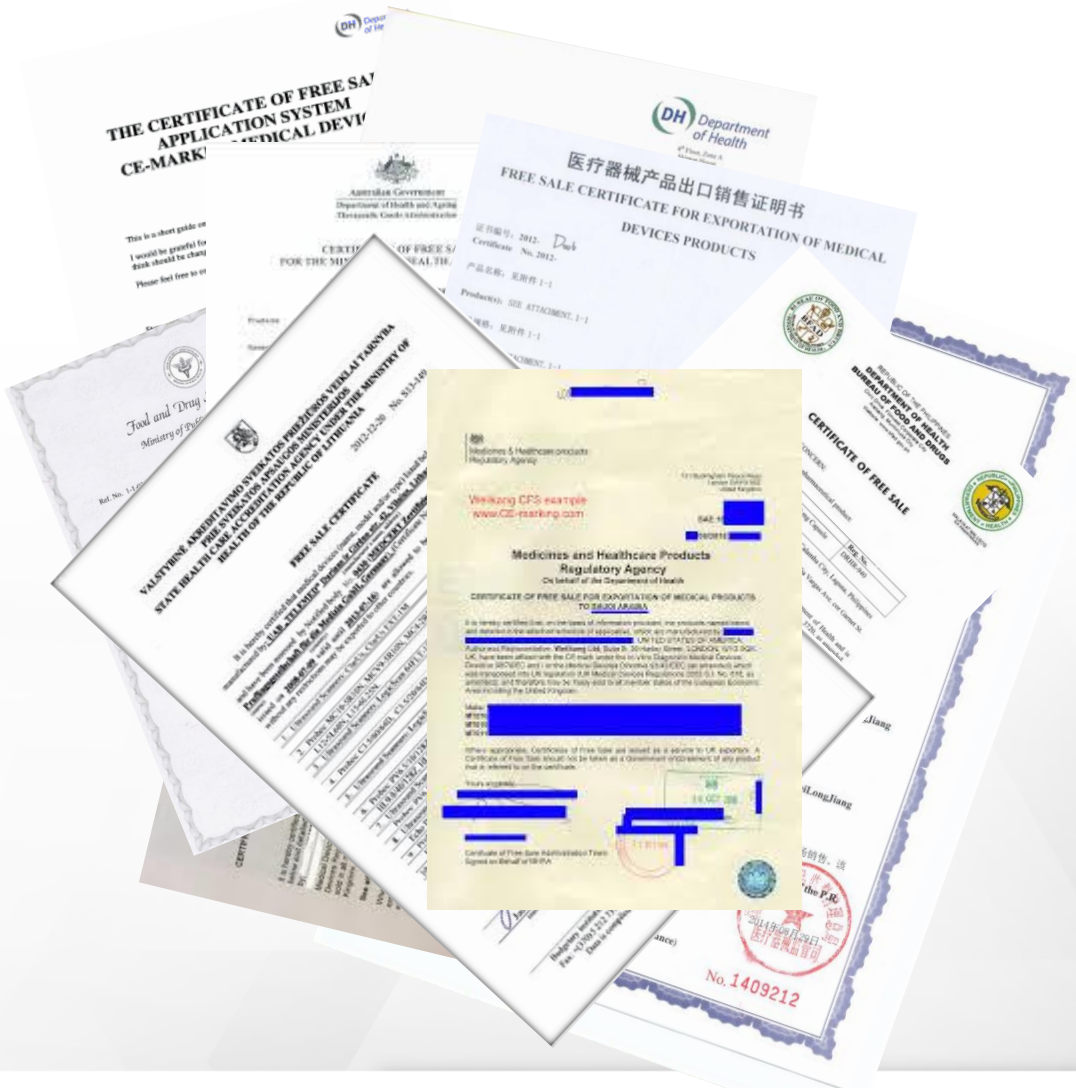
Need for a pragmatic approach to manage changes arising from the transition to EU MDR/IVDR to avoid disruptions to product supply.

MedTech Europe publications on the impact of the MDR and IVDR on international registrations

- '*Impact of changes under the new EU Medical Devices Regulation (EU) 2017/745 to international registrations*', **available** on MedTech Europe's website: https://www.medtecheurope.org/resource-library/impact-of-changes-under-the-new-eu-medical-devices-regulation-eu-2017-745-to-international-registrations/
- '*Impact of changes under the new EU IVD Regulation (EU) 2017/746 to international registrations*', **available** on MedTech Europe's website: https://www.medtecheurope.org/resource-library/impact-of-changes-under-the-new-eu-ivd-regulation-eu-2017-746-to-international-registrations/
- '***Transition to EU IVD Regulation*** *(EU) 2017/746 and* ***considerations for non-EU regulatory authorities*** *on managing the impact to product registrations*', **to be published on MedTech Europe's website soon** – final draft

Transition to EU MDR/IVDR and Certificates of Free Sale

- Certificates of Free Sale (CFS) are widely used in international trade to support medical devices and IVD registrations
- In the EU, CFS are issued by a Member State where mnfr or Authorised Rep are registered
- CFS may be issued with corresponding valid notified body certificates under the Directives or under the Regulations



Transition to EU MDR/IVDR and Certificates of Free Sale

Implementation issues

- Lack of uniform approach and fragmented implementation
- CFS guidance at national level e.g.:
  - HPRA updated Guide to Applications for Certificates of Free Sale for Medical Devices (4 February 2022)

Potential solutions

- CAMD work item on CFS
- CFS template (EU MDR Article 60/EU IVDR Article 55)

Q&A

Thank you!

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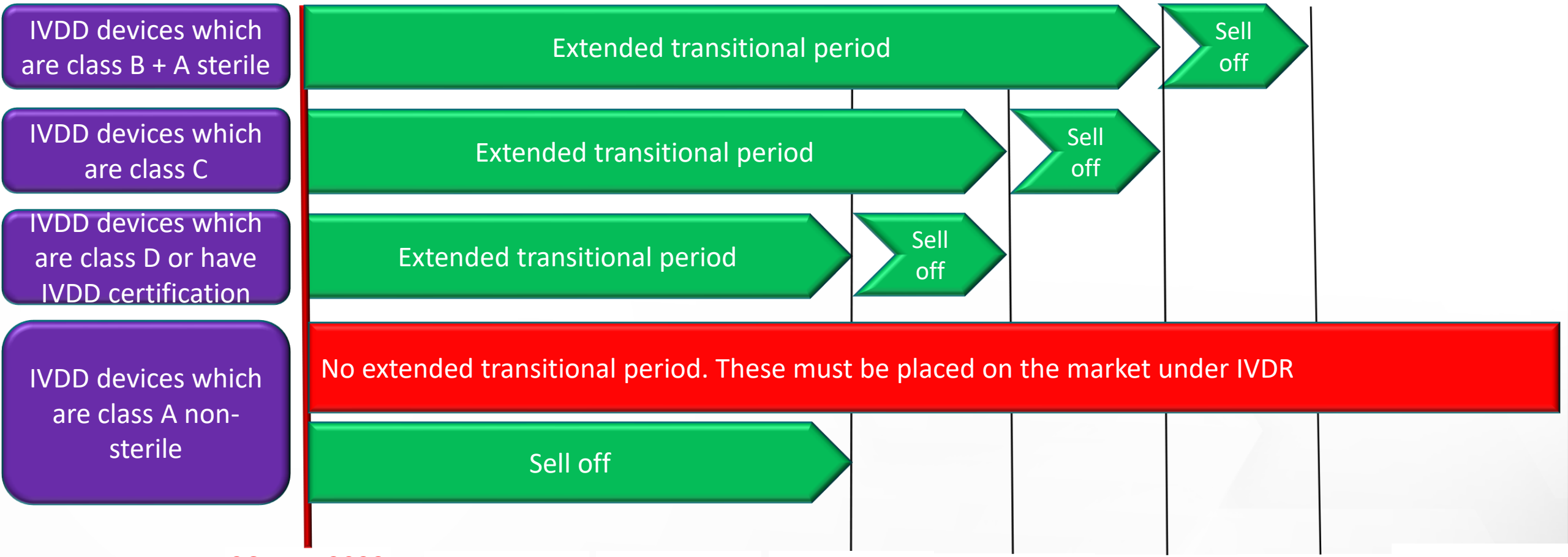
Back-up slides - IVDR

Some other transition periods impact devices

- Until EUDAMED is mandatory, legacy devices can continue to be registered as they are under IVDD
- EUDAMED is expected to become mandatory in mid-2023 *including for legacy devices*
  - +6 months to complete actor registration
  - +24 months to complete devices registration (but watch out! Vigilance may trigger early registration)

- Staggered timelines for when UDI is required on label for IVDR devices, *not* legacy devices
  - When certifying under IVDR, keep deadlines in mind

Amended transitional provisions for IVD Directive devices and other dates



UDI on **IVDR** class D label

UDI on **IVDR** class B, C label

UDI on **IVDR** class A label

EUDAMED becomes mandatory mid-2023

Actor registration + 6 months
Device registration + 24 months

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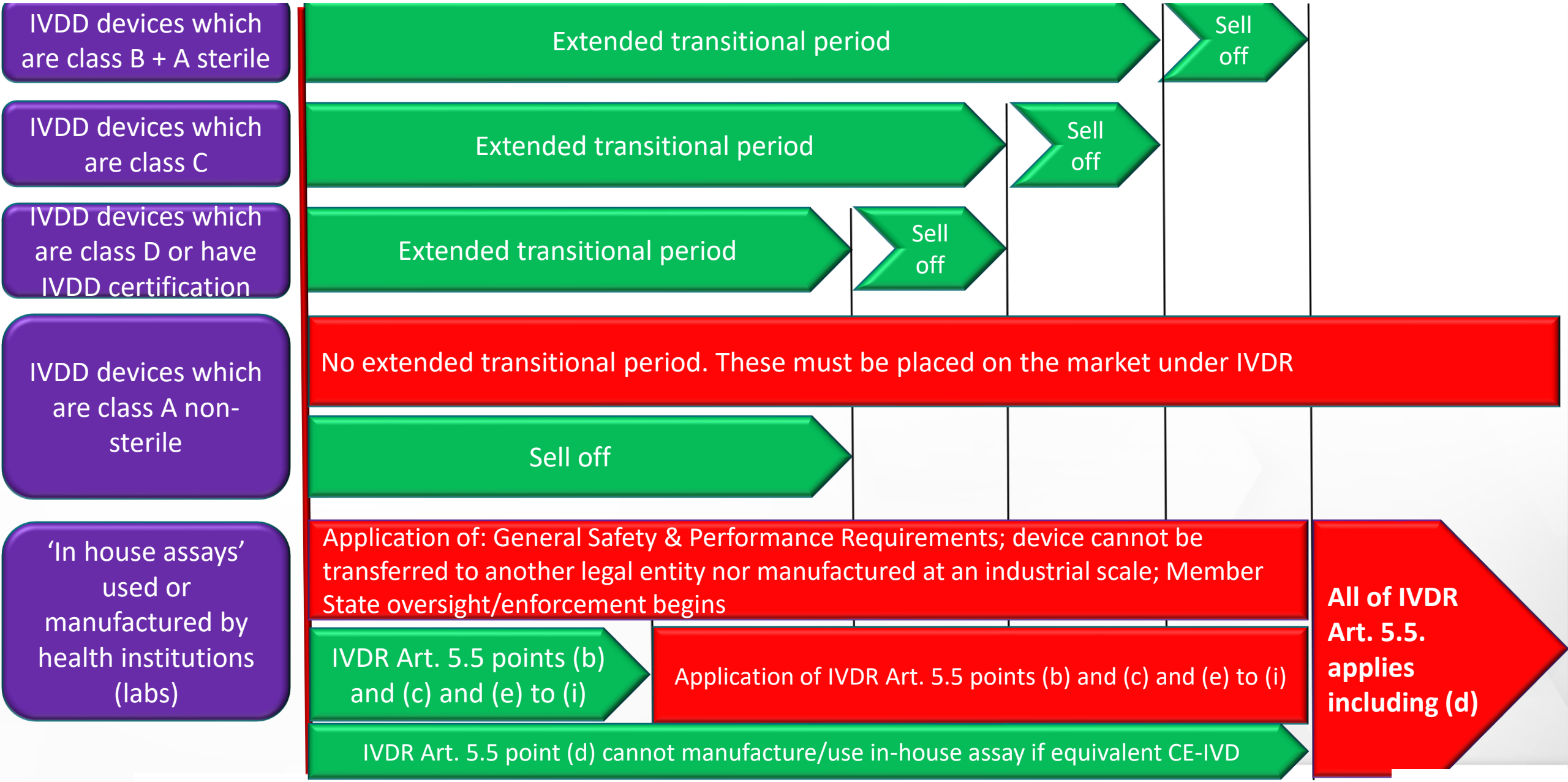
Amended transitional provisions for IVD Directive devices and in-house assays



What does this mean? Co-existence of devices or even the 'same product' with different legal statuses and requirements

	Placed on the market	Declaration of Conformity	Applicable legislation	Post market surveillance, vigilance, market surveillance, registration of actors and devices
Old devices	Before May 2022	Before May 2022	IVDD	IVDD
Legacy devices	After 26 May 2022 until end of extended transitional period in IVDR Article 110.3	Before May 2022	IVDR (and IVDD)* **IVDR Article 110.3 requires devices to comply with IVDD aside from certain IVDR requirements*	IVDR *Also: no significant change to device design and intended purpose* *Note: at time of writing, it is not yet clear whether PSUR and PMS reporting requirements will apply*
IVD Regulation devices ***(other than legacy devices)***	Before or after May 2022	Before or after May 2022	IVDR	IVDR