IVD-R

What is it?

Why does it matter to you?

What is it?

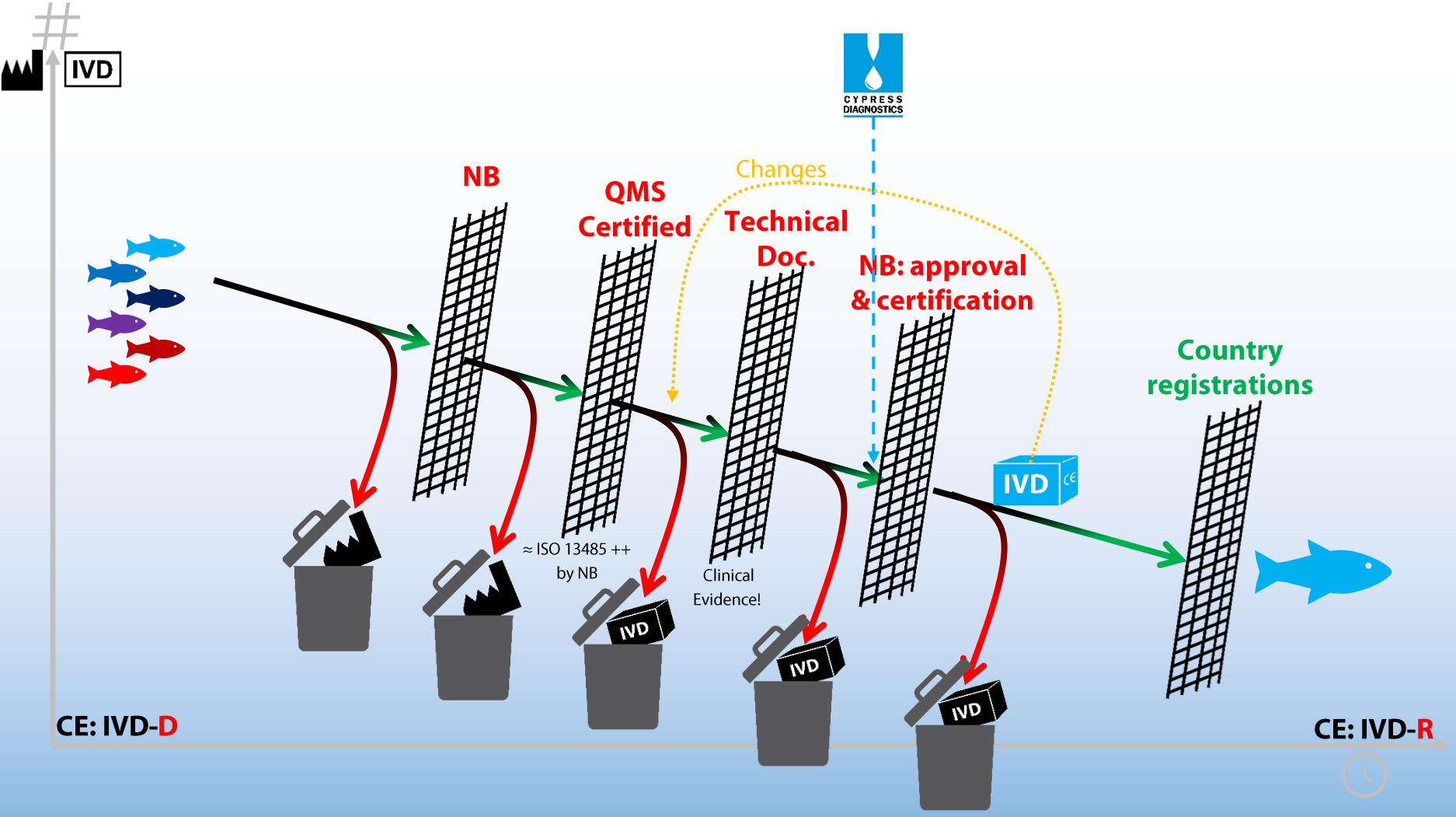
- Law
- Requirements for IVD's
- For obtaining CE marking
- For use in EU
- For EU manufacturers to obtain a Free Sales Certificate
- Replaces IVD-D

IVD-R

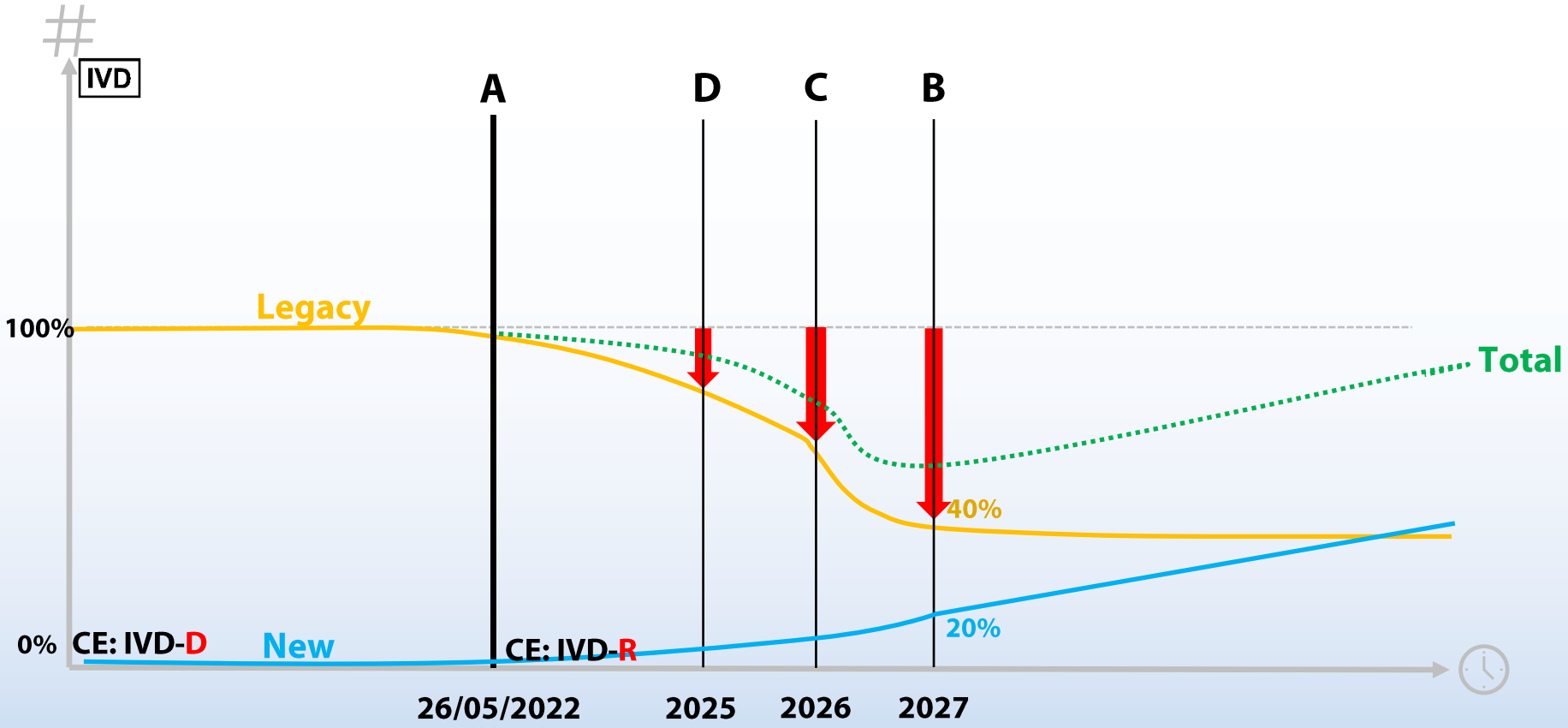
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- https://eur-lex.europa.eu/eli/reg/2017/746

What will happen?

For cat. B, C & D (85% of IVD's)



IVD-R: impact on IVD's



Less innovation
Less diversity
Less products

Are you safe?


DEKRA

CERTIFICATE

CYPRESS DIAGNOSTICS

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Cypress Diagnostics BV

Scope of certification:

Design & development, production and distribution of reagents and instruments for in-vitro diagnostic use in biochemistry, microbiology, blood grouping, coagulation, drugs of abuse, haematology, serology, bacteriology, urinalysis testing and laboratory equipment.

Certified location:

Nijverheidsstraat 8, 2235 Hulshout, Belgium

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51546-R1-00.

Certificate registration no.: 51546-14-00_EN

Certificate valid from: 2022-09-15

Certificate valid to: 2025-09-14

Natascha Jezyschek

DEKRA Certification GmbH, Stuttgart, 2022-09-15

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra.com/medical-devices

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Important questions	Cypress Diagnostics
1. Notified Body?	✓ Yes, Dekra
2. Certified QMS?	✓ Yes, certified and covering applicable IVD-R legislation
3. Product selection made?	✓ Yes, process finished
4. Technical Doc. Submission?	✓ Yes, done in November 2022
5. Product approval & certification?	✓ Glucose HBL04 expected by end 2022

What about your other partners?

IVD-R impact on distributors (IVDR, article 14)

Distributor responsibilities

- Safeguard of product integrity and storage
- Traceability
- Audit participation
- Legal after-sales service
- Reporting and NC's
- Execution of FSN
- Participation in PMS

Impact on distributors

- Cost increase
- Products & manufacturers discontinuation
- Slower innovation
- More paperwork
- Regulatory affairs department