

BSI's journey issuing the first IVDR Certificate

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bsi.

...making excellence a habit.™



Agenda

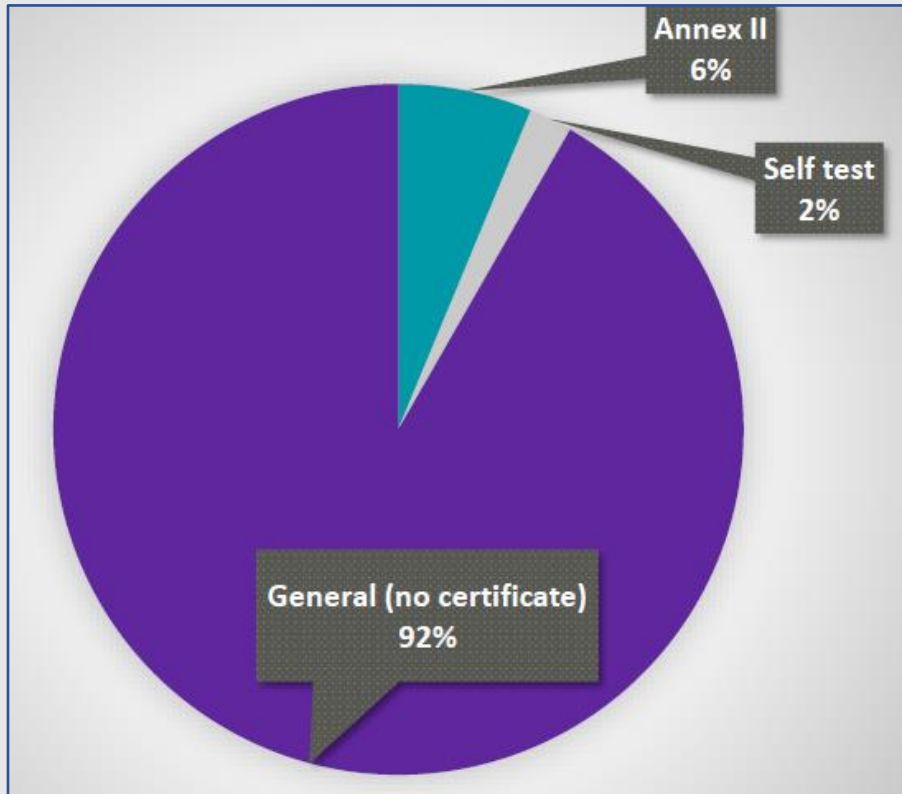
- IVDR – Infrastructure readiness?
- BSI Designation Journey
- IVDR - Where we are today?



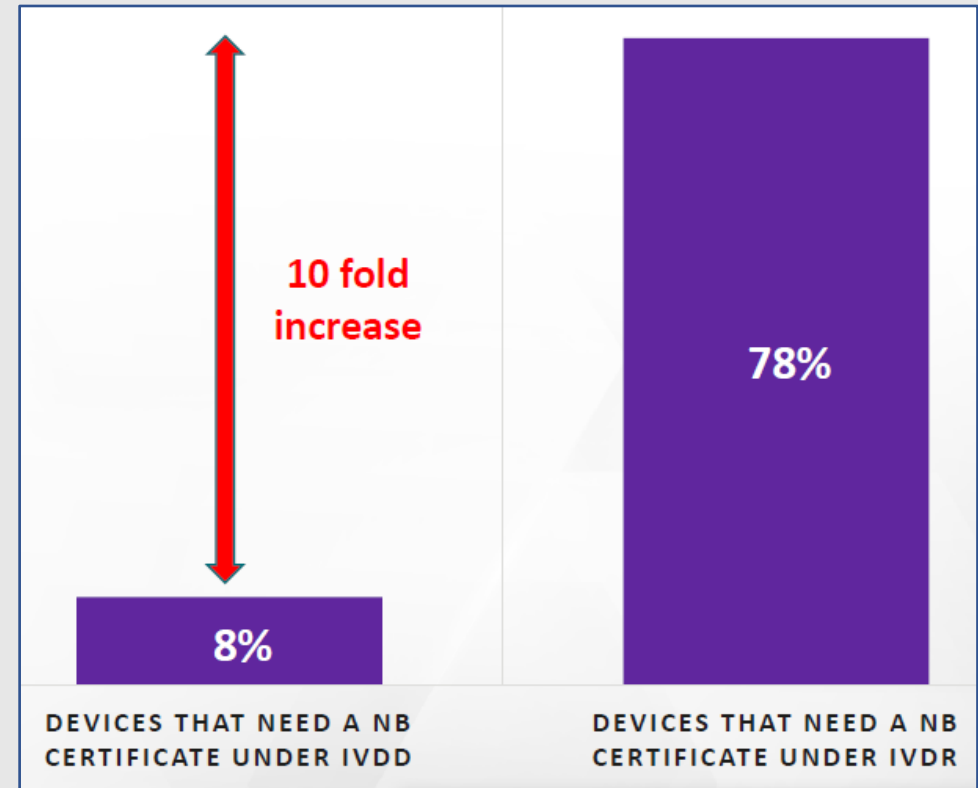
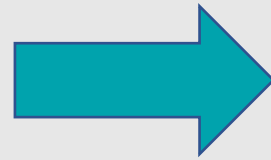


IVDR – Infrastructure readiness?

IVDR – Infrastructure readiness



Current **IVDD** certification *



IVDR certification needed *

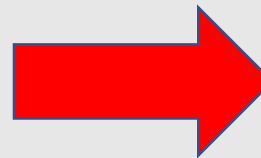
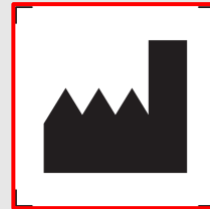
**MedTech Europe Survey Report (8th Sep 2021)*

IVDR – Infrastructure readiness

Are
You
Ready?

Stakeholders involved to achieve IVDR CE-marking

- Notified Bodies
 - ✓ Designated & operational under the IVDR > 6
- ? EU Reference Laboratories (EURL)
- EU Commission
 - ✓ MDCG group
 - ✓ Expert panel
 - ? EUDAMED



MDCG Guidance

2021 Aug: MDCG 2021-22 Clarification on “first certification for that type of device” and corresponding procedures to be followed by notified bodies

2021 Aug – Feb: MDCG 2021-21, 2021-7, 2021-2, Q&A: Covid 19 tests

2021 July: MDCG 2021-14 Explanatory note on IVDR codes

2021 April: MDCG 2021-4: Application of transitional provisions for certification of class D

Nov 2020: MDCG 2020-16: Guidance on Classification Rules

Dec 2019: MDCG 2019-13: Guidance on sampling of devices for the assessment of the technical documentation

? MDCG Guidance/Common Specifications/harmonized standards

IVDR – NBs where we are today?

Id. Number	Notified Body	Country	MDR	IVDR
0473	Intertek AMTAC Certification Services	UK	☑	
2797	BSI Product Certification	UK	☑	☑ ✓
1912	DARE!! Medical Certifications	NL	☑	
0124	DEKRA Certification GmbH	D	☑	☑ ✓
0344	DEKRA Certification B.V.	NL	☑	☑ ✓
0653	EKAPTY SA	GR	☑	
2460	DNV Nemko Presafe AS	NO	☑	
0297	DQS Medizinprodukte	D	☑	
0413	Intertek Semko	S	☑	
1984	Kiwa	TR	☑	
0459	LNE/G-MED	F	☑	☑ ✓
0088	LRQA	UK	☑	☑
0483	mdc medical device certification	D	☑	☑
0482	MEDCERT	D	☑	
0050	NSAI	IRL	☑	☑
0543	Presafe	DK	☑	☑
0120	SGS	UK	☑	☑
1304	SIQ Ljubljana	SL	☑	
2195	SZUTEST	TR	☑	
0044	TÜV Nord Cert.	D	☑	
0197	TÜV Rheinland LGA Products	D	☑	☑ ✓
0123	TÜV SÜD	D	☑	☑ ✓
0843	UL International Limited	UK	☑	☑



Body type ▲	Name ▲	Country ▲
▸ NB 2797	BSI Group The Netherlands B.V.	Netherlands
▸ NB 0344	DEKRA Certification B.V.	Netherlands
▸ NB 0124	DEKRA Certification GmbH	Germany
▸ NB 0459	GMED SAS	France
▸ NB 0197	TÜV Rheinland LGA Products GmbH	Germany
▸ NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

source: Nando (8th October 2021)

source: Team NB; MDR-IVDR-Application; 2017-10-30



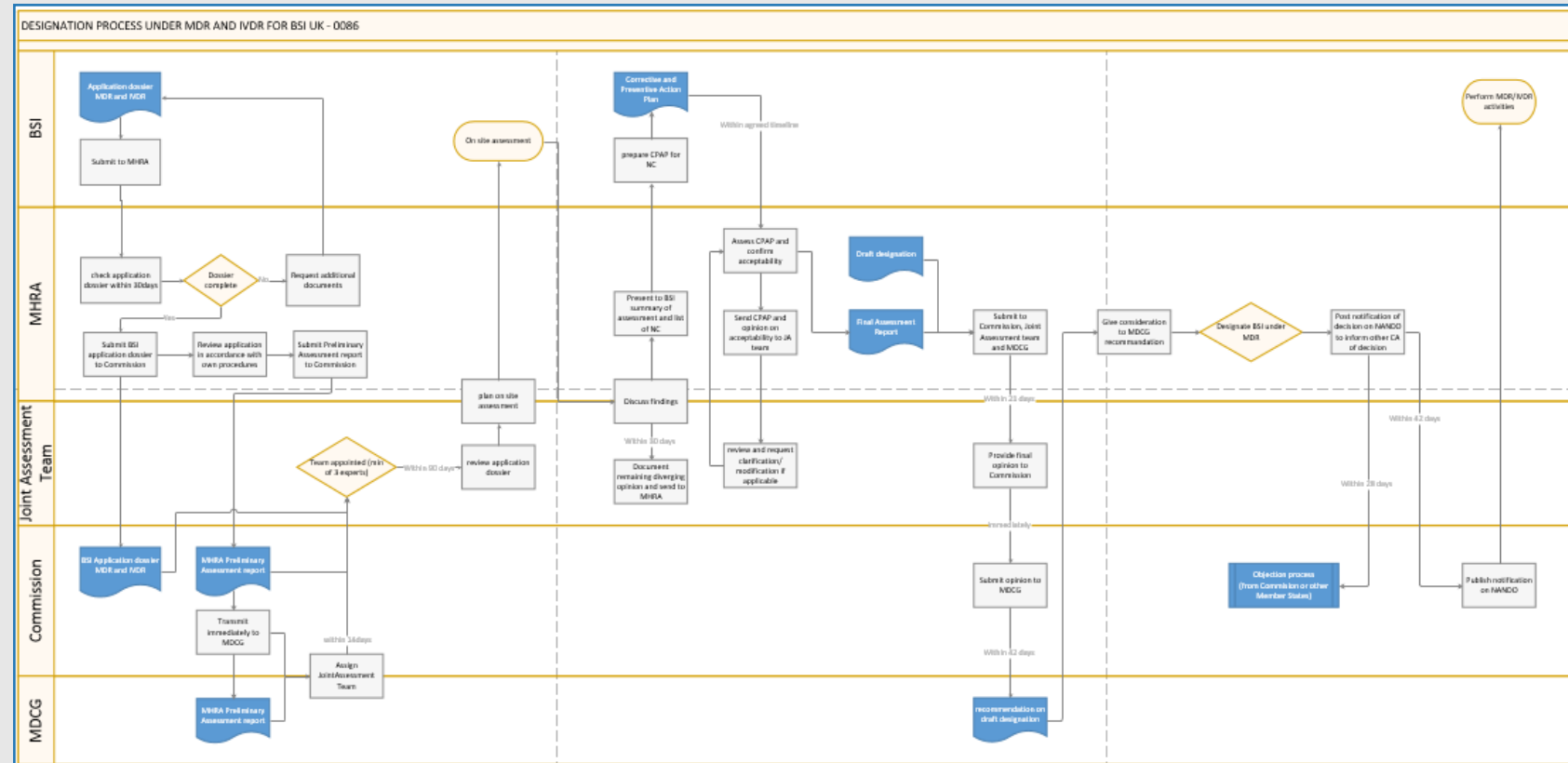
BSI Designation Journey

BSI IVDR/MDR Designation Journey

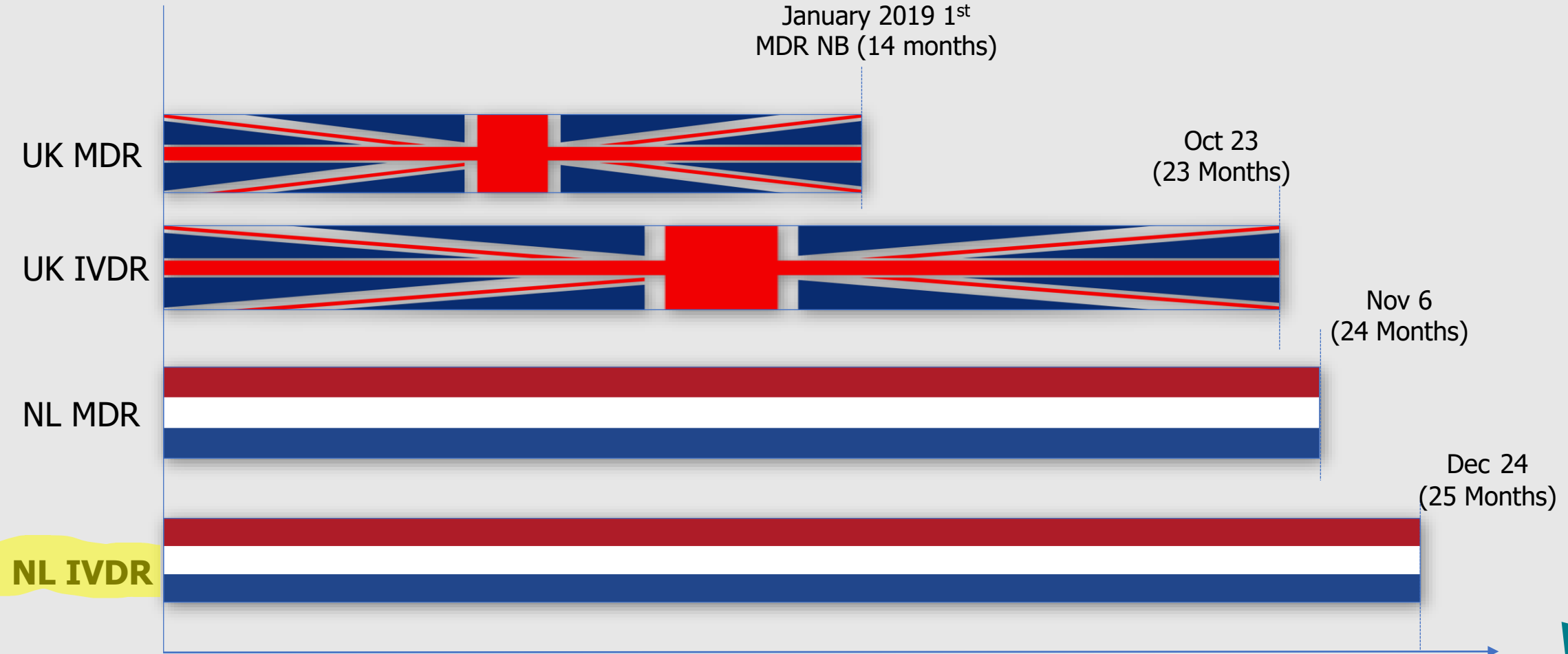
26th November 2017 - Application for IVDR/MDR submitted
(6 months after entry into force of the IVDR)

Nov 2018 JA for BSI 0086
July 2019 JA for BSI 2797

IVDR BSI 2797
24th December 2019
published on Nando



BSI – IVDR/MDR Designation Journey



1st IVDR issued!

BSI NL 2797 – IVDR readiness

- 25th May 2017 IVDR entry into force

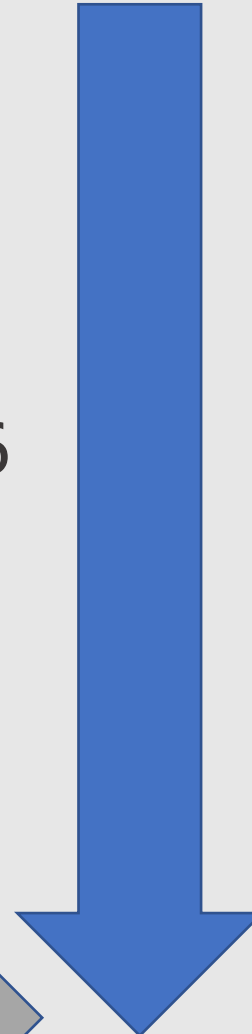


**Procedural
IVDR implementation**

- 26th November 2017 –IVDR application 0086
- 24th December 2019 – IVDR Designation
- 26th May IVDR Date of Application (DoA)

Organisational IVDR implementation

- FTE increase in QMS team
- FTE increase in Technical teams
- Building an internal & external clinician team
- FTE increase in Project Management & IT team
- FTE increase in Regulatory team

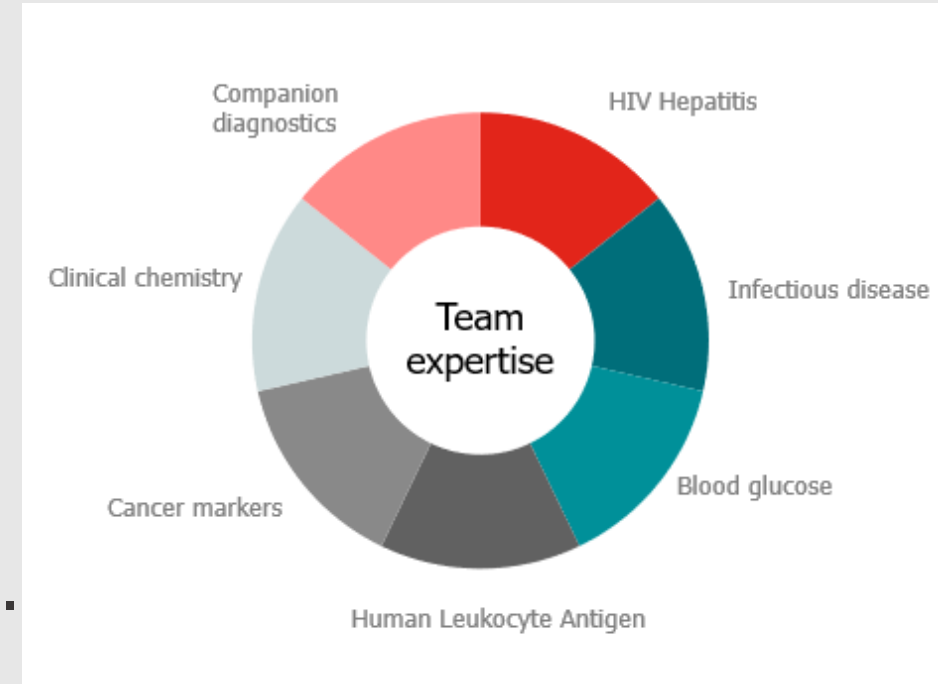


IVDD & IVDR Compliance until 27 May 2024!

Ongoing!

BSI - readiness

- **2017:** BSI IVD team consists of **6 technical experts**
- **2021:** BSI IVD team consists of **25 technical experts**, with an average of **16 years** IVD industry and regulatory experience.
- The team has a combination of clinical and regulatory expertise, including companion diagnostics, infectious disease and cancer markers.



The BSI Medical Devices
IVD team
combined experience

400
YEARS



BSI NL 2797 – IVDR readiness

- **24th December 2019** – IVDR Designation
- **January 2020** – Accepting IVDR quotes/contracts
- **February 2020** – first Technical Reviews
- **March 2020** – First IVDR QMS audit

Conformity Assessment
with **limited** Guidance!

**Covid 19
pandemic**

MDCG Guidance

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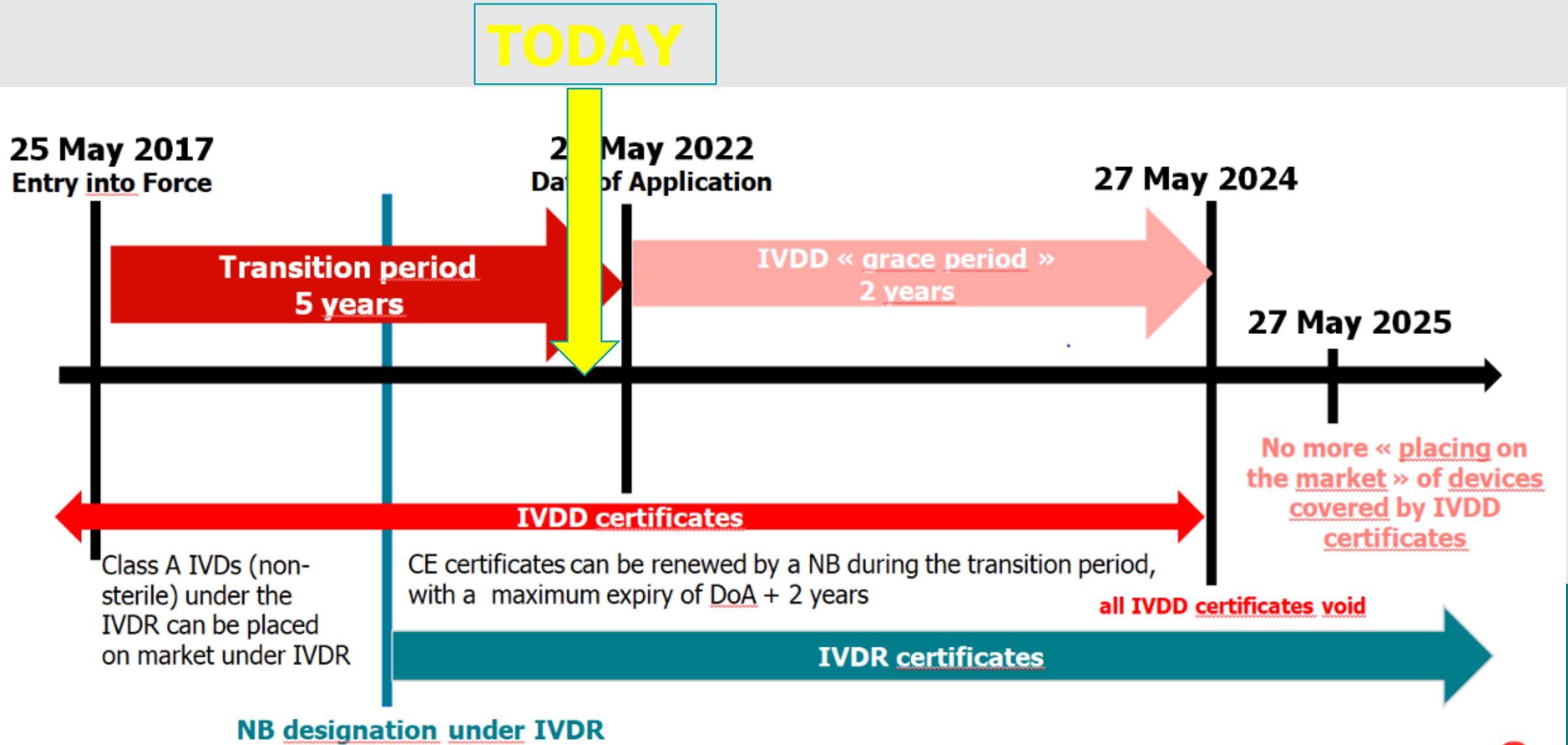
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IVDR – where we are today?

Where are we today?



Where are we today?

MDCG 2021-4 outlines options for NBs issuing Class D Certificates **without** EURL / expert panel involvement!

Class D Devices **other** than current List As

- Impact on screening on blood donations for blood transfusions/organ transplantations

Sep 2021

Dec 2021

26 May 2022

26 May 2024

CS?

EURL?

„Grace Period“

3 Sep 2021
expert panel operational

❖ 2. Ongoing consultations under the PECP

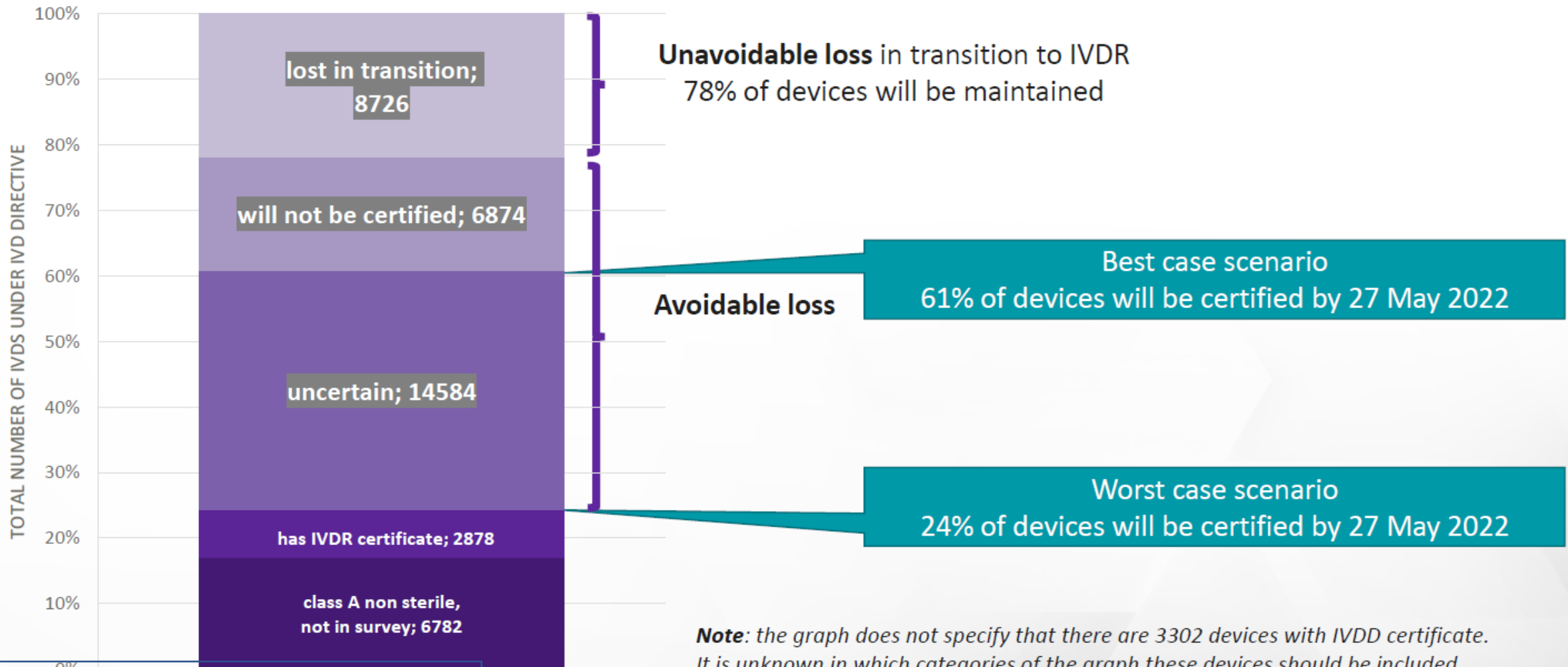
This section lists the templates describing the types of device for document MDCG 2021-22.

- IVD-2021-000001
- IVD-2021-000002
- IVD-2021-000003



Where we are today?

Forecast: % of IVDs expected to be certified under IVDR by 27 May 2022



Note: the graph does not specify that there are 3302 devices with IVDD certificate. It is unknown in which categories of the graph these devices should be included.



Thank you for your attention!