2021-03-18

IVDR Implementation – State of play

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Agenda

- Transition timelines IVDD - IVDR
- IVDR classification
- Conformity assessment infrastructure
- Development of guidance, CS etc.

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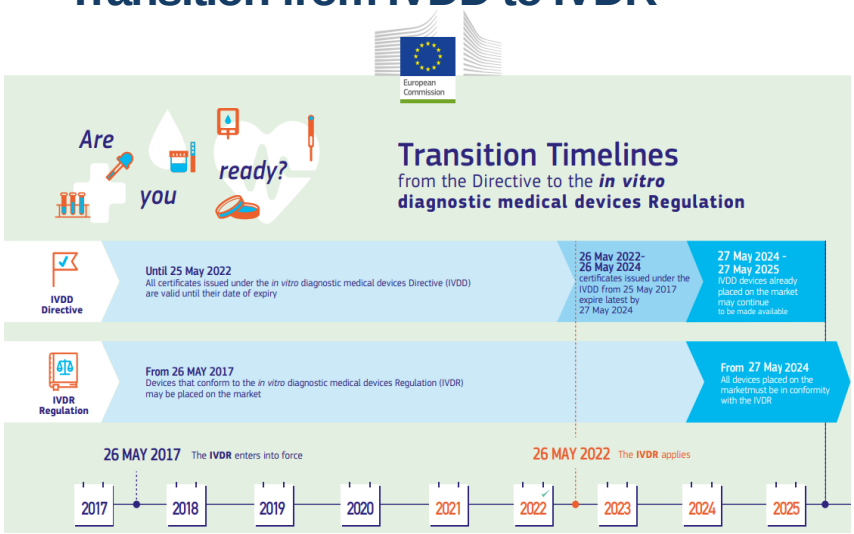
Transition from IVDD to IVDR



DoA
434 days

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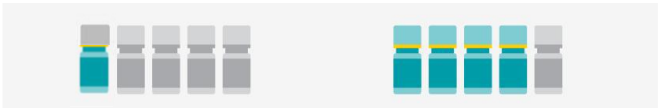
Transition from IVDD to IVDR – Notified Bodies

Expected need of notified bodies



Under IVDD
10-15 % of IVDs

Under IVDR
80-90 % of IVDs

Certificates evolution*

IVDD certificates	IVDR applications	IVDR certificates
1064	230	6

* Team-NB annual survey, with 2020 provisional data (survey completed at 81%)

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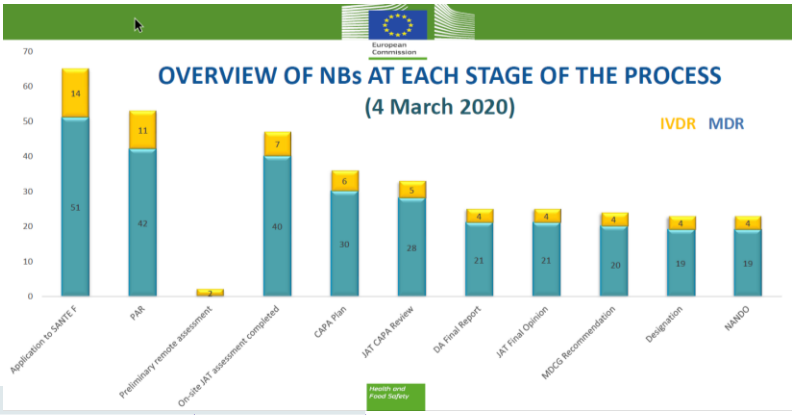
Designation of Notified Bodies IVDR - State of play

Total Applications Received
16

Applications Progressing
14(-2 UK)

(IVDR v IVDD*)
~65 %

*Excluding bodies from Turkey



Body type	Name	
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

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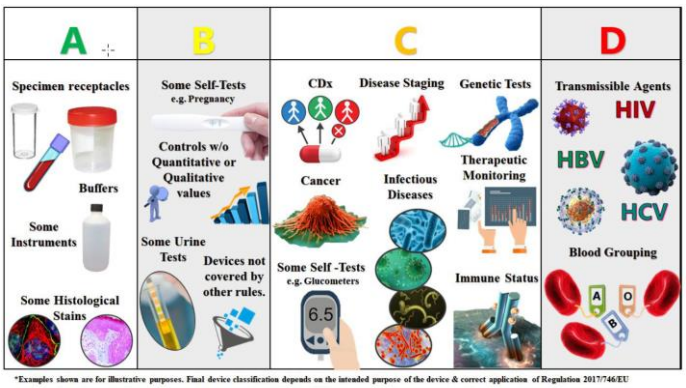
IVDR classification

	CLASS RISK LEVEL
A	**Low** Individual Risk and **Low** Public Health Risk
B	**Moderate** Individual Risk and/or **Low** Public Health Risk
C	**High** Individual Risk and/or **Moderate** Public Health Risk
D	**High** Individual Risk and **High** Public Health Risk



Courtesy of Philip Kelly HPRA

Application of the classification rules (set out in Annex VIII)
- governed by the intended purpose of the devices

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Guidance: Scope & Classification

Work item	Description	Preliminary timeline
Classification of IVDs		
Guidance on Classification Rules under Regulation (EU) 2017/746		Published MDCG 2020-16
Put in place Helsinki procedure for IVDs	Transpose the existing MDR procedure for assessing borderline and classification cases	Q2 2021

Ongoing MDCG guidance development:

mdcg_ongoing_guidancedocs_en.pdf (europa.eu)

Products required to meet Common Specifications

- Common Technical Specifications (CTS) for the IVD Directive will be transposed to CS for the IVDR.
- Annex II List A devices under the IVDD will be Class D under the IVDR (expected to comply with CTS under the current IVDD).
- Devices not listed under Annex II of the IVDD, which will become Class D devices under the IVDR.
- CS in preparation for devices that are envisaged to be Class D under the IVDR that are currently not in Annex II List A under the Directive.

Performance Evaluation

Work item	Description	Preliminary timeline
IVD common specifications (CS)		
Adoption of first round of CS	CS on the basis of the amended Decision 2002/364/EC + Chagas/syphilis, Kidd/Duffy and CMV/EBV, and possibly COVID-19	Adoption Q2-Q3 2021
Guidance on performance evaluation		
Guidance on performance evaluation	Definitions and key principles	Q2 2021
Summary of Safety and Performance (SSP)	SSP template (Class C/D according to Article 29)	Q2 2021
Guidance on state of the art of COVID-19 antibody tests	Key elements of performance evaluation modalities and performance levels, under the IVDD	Q1 2021

EURLs and Expert Panels (Class D devices)

- EURLs - verifies the performance claims of devices during the conformity assessment with the applicable CS, (or with other solutions being at least equivalent).
- EURLs - performs tests on batches or samples of the device
- Expert panels - reviews the manufacturer performance evaluation report
  - when no CS are available for a device and
  - when it is the first certification for “a type of device” placed on the market under the IVDR.

Notified Bodies & Conformity

Work item	Description	Preliminary timeline
Guidance on batch verification by notified bodies and EU reference laboratories		
Guidance on frequency of batch verification	Frequency of sending samples to the EURL	Q2 2021
In-house devices		
Guidance on conditions for in-house device	Art. 5(5) IVDR (equivalent to Art 5(5) MDR)	Q3 2021
Health crisis preparedness		
Analyse the IVDR in context of hypothetical scenarios of an urgent response to a health crisis	E.g. urgent need for class A, B, C, D device	Q2 2021

EU reference laboratories

Work item	Description	Preliminary timeline
Practical issues related to EURLs	Clarification based on text of implementing acts	continuous
Survey on EURL demand	For performance verification and for batch testing	Q1 2021
Implementing acts on tasks and criteria and on fees		Q2 2021
Issue call for application	As follows the implementing acts	Q2 2021
Complete assessment and designate the EURLs	As follows implementing acts and call	Q1 2022

MDR and IVDR implementing measures rolling plan DocsRoom - European Commission (europa.eu)

What is needed for an efficient transition?

- Harmonised standards
- Operational Expert Panels
- Common Specifications
- EU reference laboratories
- Capacity of available NBs

…….but the time to DoA is limited

Thank you for listening

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