ASSOCIATION OF MEDICAL DIAGNOSTICS MANUFACTURERS
2019 ANNUAL MEETING

Facing IVDR Challenges Panel

Chair: Carol Ryerson, PhD, Sr. Principal Advisor RCRI

Panel Members:

Karin Hughes, PhD, VP Clinical & Regulatory Strategy, Astute Medical Inc.

Richard Hughes, PhD, Regulatory Affairs Manager, The Binding Site Group Ltd

Stefan Burde, PhD, IVD Product Expert, BSI Americas

Julien Senac, PhD, Expert Unit Manager, GMED North America

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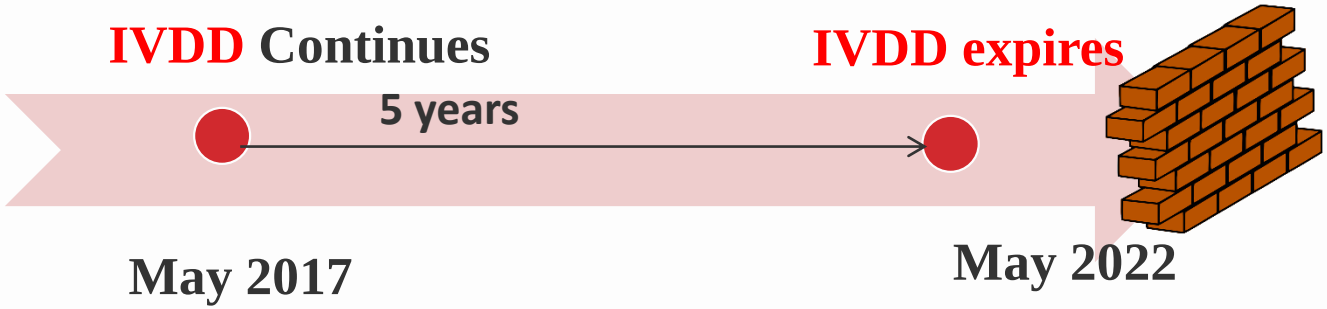
IVDD/ IVDR Timeline



IVDR Classification – some examples

Class D	Class C	Class B	Class A
• **High public health risk, high personal risk**	• **High personal risk, moderate to low public health risk**	• **Moderate to low personal risk, low public health risk**	• **Low personal risk, low public health risk**
• HIV 1/2 • Hepatitis B virus • Hepatitis C virus • HTLV I/II • Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems • CHAGAS • Syphilis screening	• Syphilis diagnosis • Neonatal screening for metabolic disorders • Rubella • Cancer markers • Genetic tests • Companion diagnostics • Blood glucose meters/ strips • Self tests	• Thyroid function • Infertility assays • Clinical chemistry • Self-test devices listed: not Class C • Note: Doctor's office tests are classified in their own right; no special classification	• Accessories • Wash buffers • Specimen receptacles • Instruments • Culture media

IVD Products - Business Impact

- There is no grandfathering. All IVD products marketed in the EU fall under IVDR.
- How will IVDR impact global new product launch plans?
- Will some products be pulled off the market?
- What will the increase in manufacturing costs be to keep products on the market in the EU?
- When is the best time to switch from IVDD to IVDR?
- How will medical practice and healthcare in the EU change?

IVDR – Biggest Challenges – Key pain points

1. Risk- based classification for all IVDs
   - IVDD: Annex II, List A, List B
   - IVDR classes are: A (low risk), B, C, D (high risk)
2. Changes in conformity assessment routes; more than 80% of IVDs will now require notified body review of Technical Documentation
3. Significantly more clinical evidence is required by IVDR
   - Is method comparison the only clinical data you have for your product? Will you need new clinical data to comply with IVDR clinical evidence requirements?
4. LDTs will require CE mark if testing EU patient samples

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