IVDR TRANSITION SOLUTION KIT

IVDD Transition to IVDR Transition

Pre Approval Approach		Life Cycle Approach	
98/79/EC IVDD	**35** Facts	**2017/746** IVDR	**101** Facts
24 Articles	**10** Annex	**113** Articles	**15** Annex

5 April 2017
EU 2017/746
For IVDR

26 May 2017
Entry into Force

05 May 2017
Publication of the new Regulation in EU Official Journal

26 May 2022
Full Application of IVDR

Key Changes in IVDR

- Expansion of Scope
- Scrutiny of notified body
- UDI and EUDAMED
- Risk based classification
- New safety & performance requirements
- More stringent clinical evidence
- Proactive and systematic PMS process
- Control on economic operators

Challenges & Solutions

Technical File Remediation (Annex I & Annex II)
- Implementation guide
- Gap Analysis tool
- Remediation SOP & templates

QMS Remediation
- Integrated QMS tool
- Remediation SOP & templates

Performance Evaluation
Implementation guide and templates for
- Scientific validity report
- Analytical performance plan and report
- Clinical performance plan and report
- Performance evaluation plan and report

Management of economic operators
- Desktop audits
- Checklists to audit vendors
- Templates – Quality Agreements

UDI & EUDAMED
- Label Management Tool
- EUDAMED Data validation tool

Post Market Surveillance
- Gap analysis tool
- PMS Process & templates

Cyient Differentiators

20 years OEM & electronic box-build experience IVD and POC devices	Integrated QMS navigator- IVDR, ISO 13485 & MDSAP	Integrated label management- USFDA & IVDR UDI	Customizable solution kit & Implementation guide