

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

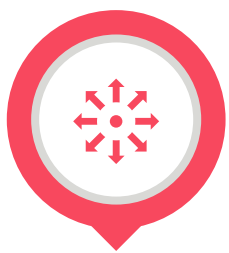
EU 2017/746
For IVDR

26 May 2017

Entry into Force



Key Changes in IVDR



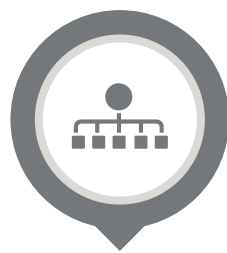
Expansion of Scope



Scrutiny of notified body



UDI and EUDAMED



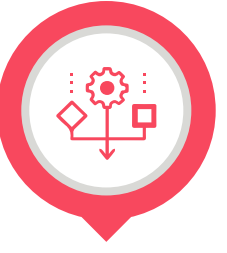
Risk based classification



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