European Union (EU) 2017/745 & (EU) 2017/746

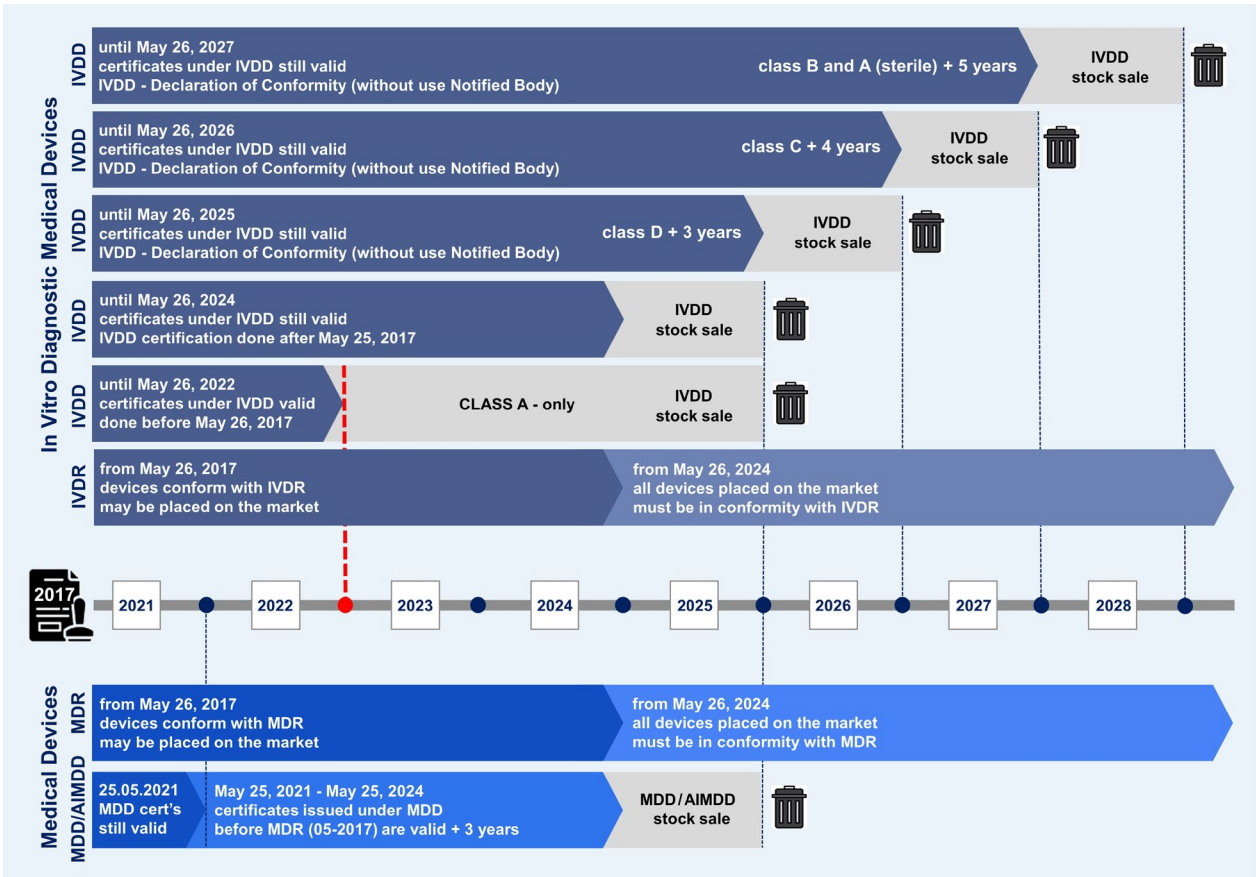
Medical Devices Regulation
In Vitro Diagnostic Medical Devices Regulation

MDR / IVDR … Final Date May 26, 2022

MDR (EU) 2017/745 is the new EU legislation and will replace the MDD 93/42/EEC & AIMDD 90/385/EEC.
IVDR (EU) 2017/746 is the new EU legislation and will replace the IVDD 98/79/EC; latest at May 26, 2022.
UDI (Unique Device Identifier) shall appear as new labeling EU identification system on all Medical Devices.
The new Regulation's definite new Risk Classes and stipulate the use of EU Notified Bodies as mandatory.

Non-EU manufacturers shall designate an EU Registered Authorised Representative.

Contact BZT-AR as your partner to be ready for the EU Medical Devices market.



IVDR & MDR Transition Timelines / Amendment December 20, 2021

Risk Classes

Examples Clinical chemistry analyzers Specimen receptacles	Class A
Examples Pregnancy self-testing Urine test strips	Class B
Examples Generic test, Pre-natal test Blood glucose self-testing	Class C
Examples Hepatitis B - blood screening HIV blood diagnose test	Class D

Notified Body

Low Risk

Self-assessment

Notified Body mandatory

High Risk

Class B

Class C

Class D

BZT-AR EU registered

Class A	• Mandate non-EU manufacturer • Verification DoC & technical files
Class B	• Provide EU registered address • EUDAMED registration
Class C	• Represent manufacturer in EU • CA inspection management • Incident & vigilance actions
Class D	• Directive / Regulation updates • Testing & NB & CFS handling

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