AtlanticKET MED

Interreg Atlantic Area
European Regional Development Fund

EUROPEAN UNION

Webinar

July 16th_2020_11:00h am CEST

New Regulatory Framework for Medical Devices and In-Vitro Diagnostic

- What does CE mark mean?
- What is a Medical Device and In-Vitro diagnostic?
- Classification system: concepts and rules
- Milestones to CE Mark

Regulatory Concepts to CE Mark under MDR or IVDR

- CE mark: Importance of the Technical documents
- General safety and performance requirements (GSPR)
- Technical standards and guidelines
- Performance evaluation under MDR / IVDR

ASPHALION

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