

# Essentials of European Medical Device Regulatory Affairs

14 May 2026



## Programme

Please note all times are in BST

Time	Presentation	Speaker
09:00	Introduction from TOPRA	TOPRA
09:05	Introduction	<b>Theresa Jeary</b> BSI Group
09:15	Scope and definitions	<b>Angela Stokes</b> Sharp Regulatory Consulting Limited
10:05	Making available on the market and putting into service of device, obligations of economic operators, reprocessing, CE marking and free movement	<b>Theresa Jeary</b>
10:40	Break	
10:55	Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European data base on medical devices.	<b>Theresa Jeary</b>
11:10	Notified bodies	<b>Theresa Jeary</b>
11:35	Classification	<b>Angela Stokes</b>
12:15	Lunch Break	
13:00	Conformity Assessment – Annex IX – XI	<b>Theresa Jeary</b>
13:45	Clinical evaluation and clinical investigation	<b>Angela Stokes</b>
14:15	Break	
14:30	Post-market surveillance vigilance and market surveillance	<b>Theresa Jeary</b>
15:05	Cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers	<b>Theresa Jeary</b>
15:15	Confidentiality, data protection, funding and penalties	<b>Theresa Jeary</b>
15:20	Final provisions	<b>Theresa Jeary</b>
15:30	Annex 1 and labelling	<b>Angela Stokes</b>
15.45	Technical documentation	<b>Theresa Jeary</b>
16:00	Close	