

# Essentials of European Medical Device Regulatory Affairs



## Programme

Please note all times are in BST (CEST -1 hour)

Time	Presentation	Speaker
09:00	Introduction from TOPRA	<b>Cristina Dragan</b> TOPRA
09:05	Introduction	<b>Theresa Jeary</b> BSI Group
09:15	Scope and definitions	<b>Janis Bayley</b> Eli Lilly & Company Ltd
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 and conformity assessment	<b>Janis Bayley</b>
12:30	Lunch Break	
13:15	Conformity Assessment – Annex IX – XI	<b>Theresa Jeary</b>
13:45	Clinical evaluation and clinical investigation	<b>Janis Bayley</b>
14:30	Break	
14:35	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>
15:10	Confidentiality, data protection, funding and penalties	<b>Janis Bayley</b>
15:15	Final provisions	<b>Janis Bayley</b>
15:20	Annex 1 and labelling	<b>Janis Bayley</b>
16:00	Close	