Essentials of European Medical Device Regulatory Affairs

Time	Presentation	Speaker
09:00	Introduction from TOPRA	TOPRA
09:05	Introduction	**Theresa Jeary** BSI Group
09:15	Scope and definitions	**Angela Stokes** 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	**Theresa Jeary**
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.	**Theresa Jeary**
11:10	Notified bodies	**Theresa Jeary**
11:35	Classification	**Angela Stokes**
12:15	Lunch Break	
13:00	Conformity Assessment – Annex IX – XI	**Theresa Jeary**
13:45	Clinical evaluation and clinical investigation	**Angela Stokes**
14:15	Break	
14:30	Post-market surveillance vigilance and market surveillance	**Theresa Jeary**
15:05	Cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers	**Theresa Jeary**
15:15	Confidentiality, data protection, funding and penalties	**Angela Stokes**
15:20	Final provisions	**Theresa Jeary**
15:30	Annex 1 and labelling	**Angela Stokes**
15.45	Technical documentation	**Theresa Jeary**
16:00	Close	