# Essentials of European Medical Device Regulatory Affairs

## Programme

**Presenters:**

- **Jacques du Preez**, Psephos Biomedica
- **Theresa Jeary**, BSI Group

| Time | Presentation | Presenter |
|---|---|---|
| 10:00 | Introduction from TOPRA | Cristina Dragan, TOPRA |
| 10:05 | Introduction | Theresa Jeary |
| 10:15 | Scope and definitions | Jacques du Preez |
| 11:00 | Making available on the market and putting into service of device, obligations of economic operators, reprocessing, CE marking and free movement | Theresa Jeary |
| 11:30 | Break | |
| 12:00 | 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 |
| 12:15 | Notified bodies | Theresa Jeary |
| 12:35 | Classification and conformity assessment | Jacques du Preez |
| 13:00 | Break | |
| 13:30 | Clinical evaluation and clinical investigation | Jacques du Preez |
| 14:10 | Postmarket surveillance vigilance and market surveillance | Theresa Jeary |
| 14:45 | Cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers | Theresa Jeary |
| 14:50 | Break | |
| 15:10 | Confidentiality, data protection, funding and penalties | Jacques du Preez |
| 15:15 | Final provisions | Theresa Jeary |
| 15:20 | Annex 1 and labelling | Jacques du Preez |
| 16:00 | Conformity assessment | Theresa Jeary |
| 17:00 | Feedback | Sammi Kwok, TOPRA |
| 17:15 | Close | |