HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agenda for
HPRA Webinar on Custom Made Devices

19th October 2023 (16:00 – 18:00)

TIME	TOPIC	PRESENTER
16:00 – 16:05	Introduction *General overview of HPRA's role as the regulator for Custom Made Devices*	Nicola Hickie (Chair) *Regulatory and Policy Manager*
16:05 – 16:35	Introduction to EU Medical Device Regulations *This session will provide an overview of the EU Medical Device Regulations with a focus on the key aspects of the regulations for custom made devices. These include the requirements for different economic operators, classification, conformity assessment, the procedure for custom made devices (Annex XIII)*	James McCarthy *Medical Device Assessor* Niamh Herlihy *Medical Device Assessor*
16:35 – 17:35	Practical impact of the regulations *A number of topics will be addressed in this session with regard to the expectations for economic operators for Quality Management Systems, technical documentation requirements, post market requirements and reporting incidents.*	Jennifer Roche *Medical Device Inspections Operations Manager* Ivana Hayes *Technology Group Lead Medical Devices*
17:35 – 17:55	Questions and Answers *Participants will be able to virtually submit questions on the day through a chat forum*	Nicola Hickie (Chair)
17:55 – 18:00	Closing	Nicola Hickie (Chair)