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COURSE CERTIFICATE

Gustav Magnusson

has participated in the half-day course

Clinical Investigation of Medical Devices - Regulatory Requirements

Presented 4 October 2022

The course covered the following topics:

- Basic overview of medical device legislations, with specific focus on the EU Medical Device Regulation (Regulation 2017/745)
- Clinical evidence
- Clinical investigation of medical devices
    - Basic requirements as stated in Regulation 2017/745
    - Additional requirements according to Swedish national law
    - Application process

Cecilia Emanuelsson

Date: 6 October 2022 Course instructor: Cecilia Emanuelsson, QAdvis AB

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Gustav Magnusson

Final Audit Report 2022-10-07

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