

Training Certificate

We hereby confirm, that

Evgeni Nikolov

has attended the following training program:

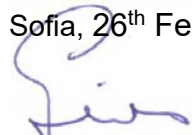
Usability and the Requirements of IEC 62366-1 and the FDA Guideline on applying Human Factors and Usability Engineering to Medical Devices

26th February 2024 in Sofia, Bulgaria

The training covered the following areas of competence

- Human-centred quality versus technology-centred quality
- The concept of innovation
- Deriving user requirements from identified user needs
- Regulatory requirements for usability (IEC 62366-1 and FDA)
- Regular use scenarios and hazard-related use scenarios
- Specifying user group profiles for a medical device
- Use-related risk analysis
- Methods for formative and summative usability evaluation
- Planning, performing and documenting summative evaluation with representative users

Sofia, 26th February 2024



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