

Grey RA declares that

Willem vd Biggelaar

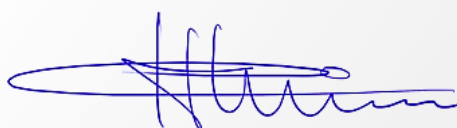
Participated on April 1 and April 2, 2019 in the medical device development workshop

IEC60601 family standards

This two-day workshop covered the following topics:

- Global regulatory requirements for medical devices
- Refresh risk management following ISO14971
- Refresh usability engineering following IEC62366-1
- Structure of the IEC60601 family of standards & selection of particulars
- General concepts of IEC60601-1:2012 including risk tracing and essential performance
- Overview of main clauses IEC60601-1:2012
- Electrical safety (clause 8)
- Making isolation diagrams
- Mechanical, thermal, radiation and other hazards
- Performing single fault analysis
- PEMS and relation with IEC62304:2015
- EMC test plans (IEC60601-1-2:2014)

Eindhoven, April 2, 2019



Paul Theunissen, trainer