CERTIFICATE

GREYRA
REGULATORY ADVICE

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