

CERTIFICATE OF PARTICIPATION

DEKRA Certification B.V. Notified Body and Registrar declares that:

Willem van den Biggelaar

has attended the training:

Conformity assessment procedures according to ISO17021:2011/2015, MDR 2017/745, associated regulatory requirements and medical device knowledge updates in Egmond aan Zee, The Netherlands on April 2-4, 2019

Including the following topics:

- Knowledge Management Updates
- Impartiality; No Conflict of Interest
- Certification Review Process
- ISO 9001:2015 / ISO 13485:2016 Updates
- Updates in DEKRA QMS
- Application Review and Planning Process, including impact on Sales Process
- Peer Review Training
- MDR / IVDR – Status of DEKRA's Planning, Qualifications, and Training
- MDR – Conformity Assessment Routes
- MDR – Auditing
- Post Market Surveillance / PSUR
- MDSAP Program Updates

DEKRA Certification B.V. Notified Body



Jennifer Bromm
Senior Project Manager/
Certification Manager



Harry van Vugt
Senior Project Manager/
Principal Certification Manager