

CERTIFICATE

Kema Quality B.V. declares that

Willem van den Biggelaar

has participated on 15-18 February 2010 in a

Training ISO 13485:2003 and auditing

Training goals:

- ISO 13485:2003 standard:
Regulatory environment; Scope of ISO 13485; Process approach; Rules for application; Requirements extensively researched; KEMA Quality approach on requirements; Use of KEMA Quality Auditor Planning Guide; Practical exercises.
- Auditing:
Principles of auditing; Audit process of KEMA Quality, BL Medical; Use of KEMA Quality Auditor Manual; Preparation of an audit; Performing an audit; Defining and documenting nonconformances; Rating of nonconformances and observations; Audit reporting; Practical exercises.
- CE auditing:
General audit process; ISO audits; Regulatory audits; CE conformity assessment routes; CMDCAS.

Arnhem, 22 March 2010

KEMA Quality B.V.



A.A.M. Laan



P.J. Reijntjes

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