CERTIFICATE

This is to certify that

Willem Biggelaar

Philips Healthcare, Eindhoven

The Netherlands

attended and completed an intensive one and a half day in house course:

Medical Device Regulations
European Union

Place: Eindhoven
Date: September 28th & 29th, 2009
Certificate: 09/74

Trainer: Peter J. Reijntjes
Qserve Consultancy B.V.

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Subjects covered during the program:

- Introduction Medical device regulation in Europe
- Medical Device Directive 93/42/EEC with a focus on
  - Amendment Directive 2007/47/EEC
  - Relation of Directive with (harmonized) standards
  - Risk Management
  - Post Market Surveillance
  - Guidance Documents
  - Classification
  - Conformity Assessment Routes
- Machine Directive 2006/42/EEC
- Clinical Evaluation
- Technical Documentation

Duration: 1,5 Days

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