



Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Roche Diabetes Care GmbH
Sandhofer Strasse 116,
68305 Mannheim
Germany**

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 4009232/A
Original Approval: 1 June 2015
Current Certificate: 1 November 2015
Certificate Expiry: 31 October 2018
LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



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EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4009232/A SCHEDULE

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

**Roche Diabetes Care GmbH
Sandhofer Strasse 116,
68305 Mannheim
Germany**

Class IIa Products

Blood Sampling Devices and associated Lancets
Pen Needles
Cartridge Systems

Class IIb Products

Diabetes Management Medical Device Software
Infusion/Injection Systems and related accessories

Schedule Issue: 01

Date of Schedule Issue: 1 November 2015

LRQA Notified Body Number 0088

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