



Lloyd's Register
LRQA

General Enquiries	T +44 (0)330 414 1271
Training	T +44 (0)330 414 1340
Client Services	T +44 (0)330 414 1353
Technical	T +44 (0)330 414 1339
New Business Enquiries	T +44 (0)330 414 1342

LRQA
Lloyd's Register Quality Assurance Limited
1 Trinity Park, Bickenhill Lane, Birmingham,
West Midlands, B37 7ES, United Kingdom
enquiries@lrqa.co.uk www.lrqa.co.uk

Global Regulatory Affairs Diabetes Care
Roche Diabetes Care GmbH
Sandhofer Straße 116
68305 Mannheim
Germany

LRQA Reference Number: 4009232

Date: 01 June 2015

Notification of Change – Update to Labelling
Accu-Chek Aviva System, Accu-Chek Performa System and Accu-Chek Inform II System
ISO 15197:2013 Compliance

The Accu-Chek Aviva, Performa and Inform II Blood Glucose Monitoring Systems have been approved by LRQA and are currently available on the market. Roche Diagnostics plan to revise the product labelling to include performance data to meet the requirements of ISO 15197:2013.

Roche submitted technical documentation and examples of labelling to LRQA, and a remote review was performed to assess if the modified labelling claims are justified and remain compliant with IVD Directive 98/79/EC.

From assessment of the technical documentation and examples of labelling submitted, the Accu-Chek Aviva, Performa and Inform II Blood Glucose Monitoring Systems and associated Test Strip IFU's are compliant with the performance requirements of ISO 15197:2013 - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

Ian Carmichael
IVD Technical Specialist
Medical Directives Team
Lloyds Register Quality Assurance Limited
Notified Body Number 0088

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