

To whom it may concern

TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich hereby states that the

ACCU-CHEK® Performa Blood Glucose Monitoring System

(including meter, test strips and control solutions)

marketed by the legal manufacturer

Roche Diagnostics GmbH (Diabetes Care) Sandhofer Strasse 116 68305 Mannheim Germany

fulfils the requirements of ISO 15197:2013 (subclause 6.3 System Accuracy). All other parts of the standard were not subject to the assessment. The evaluation is based on documents provided by the manufacturer for assessment.

The results of the review are summarized in the corresponding Assessment Result Report

MÜNCHEN

PRODUCT SERVICE

Dr. Jürgen Püls

(Order No. 713032776-01).

Munich, 2013-12-13

Ør. Dieter Schönwald

Manager In-vitro Diagnostics

PS-IVD-MUC

Dr. Jürgen Püls

Product Specialist In-vitro Diagnostics

PS-IVD-MUC

TÜV SÜD Product Service GmbH

Phon: +49 89 5008-4288 Fax: +49 89 5008-4475