



Product Service

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To whom it may concern

Munich, 2022-10-19
Order No.: 713272396

Dedicated confirmation letter for Roche Diabetes Care GmbH

We confirm the legal medical device manufacturer:

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim
GERMANY

and the fulfillment of ISO 15197:2013 /EN ISO 15197:2015 „Requirements for blood-glucose monitoring systems for self-testing“ in managing diabetes mellitus.

In 2015 the international standard ISO 15197:2013(EU: EN ISO 15197:2015) was harmonized under the respective In-vitro Diagnostic Directive (EC 98/79). With the harmonization, the standard can be utilized in the presumption of conformity assessment..

Within the most current IVD Regulation (EU 2017/746) the harmonization of this standard is still pending, but nevertheless *state of the art* for Blood glucose monitoring systems for lay use is reflected by compliance to this standard in order to obtain the CE mark at all. The evidence of providing ISO 15197 compliance, including reports on precision and accuracy, is integrated into the conformity assessment process conducted with the notified body and laid down in the EC certificate.

The EC certificates (IVDD) per Directive 98/79/EC on In Vitro Diagnostics Medical Devices, respectively the, EU Quality Management System Certificate /EU Technical Documentation Assessment Certificate (IVDR) per Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, confirm that requirements of ISO 15197 are met for the products listed below.

This holds true for all Roche Diabetes Care GmbH Accu-Chek blood glucose monitoring product families bearing the applicable CE mark:

Accu-Chek Active
 Accu-Chek Aviva
 Accu-Chek Guide
 Accu-Chek Guide Link
 Accu-Chek Guide Me
 Accu-Chek Instant
 Accu-Chek Instant S
 Accu-Chek Mobile
 Accu-Chek Performa

Randolf Köhler
 TÜV SÜD PRODUCT SERVICE GMBH
 Medical Health Services
 Foreign Affairs



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