

Certificate

Compliance of Accu-Chek Systems with the ISO15197:2013 Standard ^{1,*}

This certificate is to certify that the systems below comply with the requirements described in the ISO15197:2013 standard.



ACCU-CHEK® Aviva



ACCU-CHEK® Aviva



ACCU-CHEK® Aviva Nano



ACCU-CHEK® Aviva Expert



ACCU-CHEK® Aviva Combo



ACCU-CHEK® Aviva Insight



ACCU-CHEK® Performa



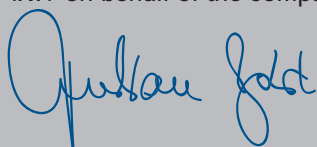
ACCU-CHEK® Performa



ACCU-CHEK® Mobile

Roche Diagnostics GmbH

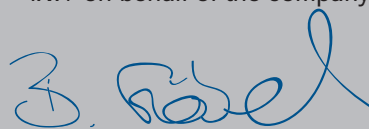
i.V. / on behalf of the company



Christian Bohrt

OUS Regulatory Affairs Diabetes Care

i.V. / on behalf of the company



Birgit Göbel

OUS Regulatory Affairs Diabetes Care

Reference:

1. International Organization for Standardization. In vitro diagnostic test systems-requirements for bloodglucose monitoring systems for self-testing in managing diabetes mellitus. Geneva, Switzerland: International Organization for Standardization; 2013.

*As assessed by LRQA (part of Lloyd's Register Group), designated as a notified body for medical devices.