



To Whom it May Concern

Manufacturer Statement

Compliance of Accu-Chek Systems with the ISO15197:2013/EN ISO15197:2015 Standard

We,

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany,

confirm that, the following products have demonstrated compliance with the ISO15197:2013/
EN ISO15197:2015:

- Accu-Chek Instant Blood Glucose Meter System

The text of international standard ISO15179:2013 has been taken over equivalently as
European standard EN ISO 15197:2015 by Technical Committee CEN/EC in 2015. The content
is identical in both standards.

Mannheim, January 21st 2021

i.V. / on behalf of the company

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Birgit Göbel
Head of OUS Submission DC

Guo-Xi Yang
OUS Regulatory Affairs Diabetes Care