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Accu-Chek Instant / Accu-Chek Instant S Blood Glucose Monitoring Systems
EN ISO 15197:2015 Compliance

The Accu-Chek Instant / Accu-Chek Instant S Blood Glucose Monitoring Systems have been approved by LRQA and are currently available on the market.

Roche Diabetes Care submitted technical documentation and copies of the labelling to LRQA, and a remote review was performed to assess if the labelling claims are justified and are compliant with IVD Directive 98/79/EC and the performance requirements of EN ISO 15197:2015.

From assessment of the technical documentation and labelling submitted, the Accu-Chek Instant / Accu-Chek Instant S Blood Glucose Monitoring Systems are compliant with IVD Directive 98/79/EC and the performance requirements of EN ISO 15197:2015 - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

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