Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-19564-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 06.07.2020

Date of issue: 06.07.2020

Holder of certificate:

Institut für Diabetestechnologie, Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm
Lise-Meitner-Str. 8/2
89081 Ulm

Tests in the fields:

Tests in the fields:	Medical devices meeting the requirements of Directive 98/79/EG² on independence
Fields of Testing / Test items:	Comparative tests in the field of clinical chemistry – POCT (Blood glucose meters)

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH. https://www.dakks.de/en/content/accredited-bodies-dakks

Area of testing	Object of examination Product (category)	Type of Test	Corpus of legislation Test procedure
Comparative tests Clinical chemistry - POCT	Blood glucose monitoring systems intended for self-testing in managing diabetes mellitus	Performance evaluation - Analytical performance evaluation • Measurement precision (Repeatability and intermediate measurement precision) • System accuracy • Influence quantities (packed cell volume effects) • Influence quantities (Interference testing) - User performance evaluation	DIN EN ISO 15197 CO-IVD-05_Wiederholpräz-15197 CO-IVD-04_IntermP-15197 CO-IVD-06_SysAcc-15197 CO-IVD-02_HCT-15197 CO-IVD-03_Interf-15197- CO-IVD-07_UserP-15197 Further applicable: DIN EN 13612

Rules and regulations

DIN EN 13612 : 2002-08	Performance evaluation of in vitro diagnostic medical devices
IN EN ISO 15197: 2015-12	In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
CO-IVD-06_SysAcc-15197 10.02.2020	Bewertung der Systemgenauigkeit in Anlehnung an ISO 15197:2013 / EN ISO 15197:2015
CO-IVD-05_Wiederholpräz-15197 10.02.2020	Bewertung der Wiederholpräzision in Anlehnung an ISO 15197:2013 / EN ISO 15197:2015
CO-IVD-07_UserP-15197 10.02.2020	Leistungsbewertung durch den Anwender in Anlehnung an ISO 15197:2013 / EN ISO 15197:2015

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CO-IVD-04_IntermP-15197 10.02.2020	Bewertung der Zwischenpräzision von Messungen in Anlehnung an ISO 15197:2013 / EN ISO 15197:2015
CO-IVD-02_HCT-15197 10.02.2020	Bewertung des gepackten Zellvolumens als Einflussgröße in Anlehnung an ISO 15197:2013 / EN ISO 15197:2015
CO-IVD-03_Interf-15197 10.02.2020	Prüfung auf Störeinflüsse in Anlehnung an ISO 15197:2013 / EN ISO 15197:2015

Abbreviations used:

CO-IVD-	In house method of the CAB
DIN	Deutsches Institut für Normung e.V.
EN	European Standard
ISO	International Organization for Standardization
POCT	Point of care testing

[1] DIN EN ISO/IEC 17025: 2018-03 General requirements for the competence of testing and calibration laboratories
[2] Directive 98/79/EG of the Council of 14 June 1993 on in vitro diagnostic medical devices.

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