

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-19564-01-00 according to DIN EN ISO/IEC 17025:2005¹ and 98/79/EC²

Period of validity: 23.04.2019 to 10.03.2020

Date of issue: 23.04.2019

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:

Medical devices

Fields of Testing/test items:

Comparative tests for proof of conformity for blood
glucose monitoring systems

Abbreviations used: see last page

Area of testing	Object of examination Product (category)	Type of Test	Corpus of legislation Test procedure
Comparative tests	Blood glucose monitoring systems intended for self-testing in managing diabetes mellitus	Performance evaluation <ul style="list-style-type: none"> - Analytical performance evaluation <ul style="list-style-type: none"> • 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 PD_65_Wiederholpräz-15197-2013 PD_67_Zwischenpräz-15197-2013 PD_63_Durchf_SysAcc-15197-2013 PD_64_Eval-15197-2013 PD_68_HCT-15197-2013 PD_70_Interf-15197-2013 PD_66_Durchf_UserEvaluation-15197-2013 Further applicable: DIN EN 13612

Rules and regulations

DIN EN 13612 : 2002-08

Performance evaluation of in vitro diagnostic medical devices

DIN EN ISO 15197: 2015-12

In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

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PD_63_Durchf_SysAcc-15197-2013	PD_63 Performance of projects following ISO 15197:2013(E)
PD_64_Eval-15197-2013	PD_64 Evaluation of projects following ISO 15197:2013(E)
PD_65_Wiederholpräz-15197-2013	PD_65 Evaluation of repeatability following ISO 15197:2013(E)
PD_66_Durchf_UserEvaluation-15197-2013	PD_66 Performance of user evaluation ISO 15197:2013(E)
PD_67_Zwischenpräz-15197-2013	PD_67 Evaluation of intermediate measurement precision following ISO 15197:2013(E)
PD_68_HCT-15197-2013	PD_68 Evaluation of packed cell volume effects as influence quantity following ISO 15197:2013(E)
PD_70_Interf-15197-2013	PD_70 Evaluation of interfering substances as influence quantity following ISO 15197:2013(E)

Abbreviations used:

DIN	German Institute for Standardization
EN	European Standard
ISO	International Organization for Standardization
PD_	PD = Project Performance Standard Operating Procedures of the Institut für Diabetestechnologie, Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm

¹ DIN EN ISO/IEC 17025: 2005-08 General requirements for the competence of testing and calibration laboratories

² Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices.