

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-22341-01-01 according to DIN EN ISO/IEC 17025:2018

Valid from: 03.08.2026

Date of issue: 03.08.2026

This annex is part of the Accreditation Certificate D-PL-22341-01-00.

Holder of the Accreditation Certificate:

ac.biomed GmbH
Pauwelsstr. 17, 52074 Aachen

with the location

ac.biomed GmbH
Pauwelsstr. 17, 52074 Aachen

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Physical testing of medical devices

outside of a recognition according to § 18 Medical Device Law Implementation Act.

*This annex to the certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS) and is digitally sealed.
This annex to the certificate is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).*

Pauwelsstr. 17, 52074 Aachen

Testing field	Device under testing device(category)	Type of testing testing	standard testing procedure
Physical testing	Cardiac valve prostheses	Durability testing - Accelerated Wear Testing (AWT) - Dynamic Failure Mode Testing (DFM)	DIN EN ISO 5840-1
		hydrodynamic performance characterization - Steady Forward Flow Testing (SFF) - Steady Back Flow Leakage Testing (SBL)	DIN EN ISO 5840-1
	Cardiac valve prostheses - Surgically implanted - Minimally invasive implanted	Verification of hydrodynamic performance	
		Pulsatile-Flow Testing	DIN EN ISO 5840-2
		Pulsatile-Flow Testing	DIN EN ISO 5840-3 Accompanying DIN EN ISO 5840-1
	Blood gas exchangers (Oxygenators)	Performance characteristics - Oxygen - and carbon dioxide-transfer rates	DIN EN ISO 7199 PA_GT
		- Heat exchanger performance factor	PA_HE-ISO-7199-2024

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Testing field	Device under testing device(category)	Type of testing testing	standard testing procedure
Physical testing	Blood gas exchangers (Oxygenators)	Performance characteristics - in vitro characteristic of physical-chemical blood parameters	DIN EN ISO 7199 PA_OH Accompanying: FDA Guidance Nov 13, 2000
	Medical devices cannulae for extracorporeal circulation	Performance characteristics - in vitro characteristic of physical chemical blood parameters	ISO 18193 PA_CH
	Medical devices Blood pumps	Performance characteristics - in vitro characteristic of physical chemical blood parameters - cavitation	DIN EN ISO 14708-5 ISO 18242 ASTM F1841 PA_PH PA_PC Accompanying: ASTM F1830

List of sources for standards:

DIN EN ISO 5840-1 : 2025-10	Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements (ISO 5840-1:2021 + Amd 1:2025); German version EN ISO 5840-1:2021 + A1:2025
DIN EN ISO 5840-2 : 2025-10	Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes (ISO 5840-2:2021 + Amd 1:2025); German version EN ISO 5840-2:2021 + A1:2025
DIN EN ISO 5840-3 : 2025-10	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques (ISO 5840-3:2021 + Amd 1:2025); German version EN ISO 5840-3:2021 + A1:2025
DIN EN ISO 7199 2025-12	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) (ISO 7199:2024); German version EN ISO 7199:2024
DIN EN ISO 14708-5:2022-12	Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices (ISO 14708-5:2020); German version EN ISO 14708-5:2022
ISO 18193 : 2021-08 / AMD1:2025-07	Cardiovascular implants and artificial organs - Cannulae for extracorporeal circulation
ISO 18242 : 2016-09 / AMD1:2023-08	Cardiovascular implants and extracorporeal systems - Centrifugal blood pumps / Amendment 1: Worst-case conditions for testing
ASTM F1830-19 (2024)	Standard Practice for Collection and Preparation of Blood for Dynamic in vitro Evaluation of Hemolysis in Blood Pumps
ASTM F1841-25	Standard Practice for Assessment of Hemolysis in Blood Pumps
FDA Guidance 13.11.2000	Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff
PA_GT_Rev02	Evaluation of gas transfer rates and pressure drop of oxygenators according to ISO 7199:2024 and FDA Guidance for Cardiopulmonary Bypass Oxygenators 510(k): 2000
PA_OH_Rev02	Evaluation of hemolysis of oxygenators according to ISO 7199:2024 and FDA Guidance for Cardiopulmonary Bypass Oxygenators 510(k):2000
PA_CH_Rev01	Evaluation of hemolysis of cannulas according to ISO 18193:2021
PA_HE-ISO-7199-2024_Rev01	Evaluation of heat exchanger performance factors of oxygenators according to ISO 7199:2024 and FDA Guidance for Cardiopulmonary Bypass Oxygenators 510(k):2000
PA_PC_Rev00	Evaluation of cavitation tendency in centrifugal blood pumps according to ISO 18242:2016/Amd.1:2023

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PA_PH_Rev02

Evaluation of hemolysis in blood pumps according to ASTM F1841-25 & ISO 14708-5:2020 & ISO 18242:2016/Amd.1:2023

Abbreviations used:

DIN	German institute for standardization
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
FDA	Food and Drug Administration
PA	testing procedure of ac.biomed GmbH