Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 2512862-1
Certificate Holder:	VELLAP Diagnostics GmbH Industriestr. 8 99427 Weimar Germany
Scope:	Design and development, manufacture and distribution of immunoassays, in vitro diagnostic reagents, in vitro diagnostic test kits used in the diagnosis, management and/or detection of allergies, autoimmune status, blood analytes, cardiac markers, coagulation, cancer, drugs of abuse, endocrine disorders, fertility testing, immune status, infectious diseases, inflammatory markers, pregnancy testing, protein metabolism, rheumathoid marker including home use and near patient/point of care.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	1160415-40
Effective date:	2025-07-07
Expiry date:	2028-07-06
Issue date:	2025-07-07

This certificate can be validated on https://www.certipedia.com

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