

Certificate

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

Registration No.: SX 1469080-1
Certificate Holder: LIONEX GmbH
Salzdahlumer Str. 196
38126 Braunschweig
Germany

Scope: Design and development, manufacture and distribution of in-vitro diagnostic reagents and test kits based on ELISA and rapid tests for the infectious diseases, inflammatory and thrombosis related markers.

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.: 1169509-100
Effective date: 2025-01-10
Expiry date: 2028-01-09
Issue date: 2024-12-02
Replaces certificate SX 1469080-1 issued 2022-01-13



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