

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1654629-1

Certificate Holder: Senova Gesellschaft für Biowissenschaft und Technik mbH
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.: 1172086-10

Effective date: 2024-12-20

Expiry date: 2027-11-04

Issue date: 2024-12-20

Replaces certificate SX 1654629-1 issued 2021-11-19



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

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