

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1624072-1

Certificate Holder: Seramun Diagnostica GmbH
Spreenhagener Str. 1
15754 Heideseesee
Germany

Scope: Design and development, manufacture and distribution of in-vitro diagnostics and laboratory systems, comprising laboratory equipment and software, for the immunological detection of autoimmune and infectious diseases

Design and development, manufacture and distribution of substrates, stabilizers, antigens and antibodies for in-vitro diagnostics

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.: 1145801-40


Effective date: 2024-03-10

Expiry date: 2027-03-09

Issue date: 2024-03-04

Replaces certificate SX 1624072-1 issued 2021-03-03

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


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