

Certificate

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

Registration No.: SX 1763647-1

Certificate Holder: ScheBo Biotech AG
Netanyastr. 3 - 5
35394 Gießen
Germany

Scope: Design and development, manufacture, distribution of in-vitro diagnostic test kits including near patient/point of care in-vitro diagnostic medical devices used in the diagnosis and management of gastrointestinal diseases, cancer screening, and the monitoring of different cancers.
Design and development, manufacture and distribution of in-vitro diagnostic devices used for human stool sample preparation.

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.: 1197255-100

Effective date: 2026-01-27

Expiry date: 2027-09-02

Issue date: 2026-02-12

Replaces certificate SX 1763647-1 issued 2026-01-27



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