

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1217742-1

Organization: Chembio Diagnostics GmbH
Schwarzschildstr. 1
12489 Berlin
Germany

Scope: Design and development, manufacture and distribution of instruments used in combination with in vitro diagnostic lateral flow assays

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.

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