

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1081420-1

Organization: Lophius Biosciences GmbH
Am BioPark 13
93053 Regensburg
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic immunoassays for the determination of the immune status.

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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Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany