Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1512506-1

Organization: Siemens Healthcare Diagnostics
Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic medical devices (reagents, controls, instruments and software) used in the detection of plasma proteins and management of hemostasis

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.: 1086320-40
Effective date: 2021-08-16
Expiry date: 2024-08-15
Issue date: 2021-08-06

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg Germany	Design, development and manufacture of in vitro diagnostic reagents and controls
/02	c/o Siemens Healthcare Diagnostics Products GmbH Am Kronberger Hang 3 65824 Schwalbach Germany	Design and development of in vitro diagnostic instruments and software
/03	c/o Siemens Healthcare Diagnostics Products GmbH Antwerpener Str. 1 47229 Duisburg Germany	Warehousing and distribution of in vitro diagnostic reagents and controls
/04	c/o Siemens Healthcare SA/NV Guido Gezellestraat 125 1654 Beersel/Huizingen Belgium	Warehousing and distribution of in vitro diagnostic instruments and software

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