

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Sysmex Europe GmbH
Mainstr. 7
24539 Neumünster
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Manufacturing of in vitro diagnostic reagents for
hematology, urinalysis and coagulation**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-05-27
Certificate Registration No.: SX 60128609 0001
An audit was performed. Report No.: 21233978 004
This Certificate is valid until: 2021-05-26

Certification Body



Date 2018-05-09



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety