Certificate

Quality Management System
EN ISO 13485:2016

Registration No.	SX 2421945-1
Certificate Holder	Sysmex Europe SE Bornbarch 1 22848 Norderstedt Germany
Scope	Manufacturing of in vitro diagnostic reagents for Haematology, Clinical Chemistry and Haemostasis. Design, development and manufacture of software for sample data analysis in the area of Haematology, Haemostasis, Immunohaematology, Chemistry, Immunochemistry and Clinical Chemistry. Design, development and manufacture of buffer solutions for blood cell staining for in vitro diagnostic use. Distribution and service of instruments, reagents and accessories for In vitro diagnostic use for the fields of: - Haematology, Haemostasis, Immunohaematology, Histology, Cytology - Chemistry, Immunochemistry, Clinical Chemistry - Molecular diagnostics - Products for Laboratory Automation Distribution of magnetic sensing devices, probes, associated equipment and sterile magnetic markers.

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.	1131422-10
Effective date	2023-09-25
Expiry date	2025-05-16
Issue date	2023-09-25

Replaces certificate SX 2421945-1 issued 2023-02-07

This certificate can be validated on https://www.certipedia.com

Dr. M. Fischer
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland® Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.	SX 2421945-1
Certificate Holder	Sysmex Europe SE Bornbarch 1 22848 Norderstedt Germany

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Sysmex Europe SE Bornbarch 1 22848 Norderstedt Germany	Design and development, manufacture, distribution and service
/02	c/o Sysmex Europe SE Bornbarch 3 22848 Norderstedt Germany	Technical service and quality control of reagents as well as design and development and manufacturing of software for In vitro diagnostic use
/03	c/o Sysmex Europe SE Bornbarch 4 22848 Norderstedt Germany	Service and regulatory issues, design and development, technical product management
/04	c/o Sysmex Europe SE Bornbarch 5 22848 Norderstedt Germany	Quality control
/05	c/o Sysmex Europe SE Bornbarch 8 22848 Norderstedt Germany	Distribution and service
/06	c/o Sysmex Europe SE Bornbarch 10 22848 Norderstedt Germany	Distribution and service as well as design and development

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Certificate Holder	Sysmex Europe SE Bornbarch 1 22848 Norderstedt Germany

The scope of certification also covers the following sites:

/07	c/o Sysmex Europe SE Mainstr. 7 24539 Neumünster Germany	Manufacturing of in vitro diagnostic reagents

Report No.	1131422-10
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