

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2421945-1

Organization: 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.: 1112500-20
Effective date: 2022-05-17
Expiry date: 2023-05-16
Issue date: 2022-05-16

A handwritten signature in blue ink, appearing to read 'A. Fechner'.



Dipl.-Ing. A. Fechner
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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EN ISO 13485:2016**

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The scope of certification also covers the following:

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 as well as design and development
/04	c/o Sysmex Europe SE Bornbarch 5 22848 Norderstedt Germany	Quality control

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The scope of certification also covers the following:

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

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