

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**  
**EN ISO 13485:2016/AC:2018**  
**EN ISO 13485:2016/A11:2021**

Registration No.: SX 2421945-1  
Certificate Holder: Sysmex Europe SE  
Deelböge 19 D  
22297 Hamburg  
Germany

Scope: Manufacture of in-vitro diagnostic reagents used in the detection of blood, urine, and body fluid analytes including near patient/point of care in-vitro diagnostic medical devices.

Design, development and manufacture of in-vitro diagnostic software used in the management of analytical data and workflow output generated by IVD devices.

Design, development and manufacture of in-vitro diagnostic reagent used in the detection of blood and body fluid analytes.

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.: 1186021-20  
Effective date: 2025-10-21  
Expiry date: 2028-05-16  
Issue date: 2025-10-21  
Replaces certificate SX 2421945-1 issued 2025-10-09



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Distribution and service of in-vitro diagnostic analyzers, reagents and accessories used in the detection of

- autoimmune status,
- blood analytes,
- blood components,
- cardiac markers,
- coagulation,
- immune status,
- immunophenotyping,
- transmissible agents,
- urine analytes,
- cancer,
- disease status,
- mRNA in surgically removed lymph nodes
- genetic testing.

Distribution of magnetic sensing devices, probes, associated equipment and sterile magnetic markers for the areas of radiology and oncology (MD).

Design, development and manufacture of in-vitro diagnostic tests used in the diagnosis, management and detection of cancer and genetic testing.

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Sysmex Europe SE Deelböge 19 D 22297 Hamburg Germany	Administration and provision of assay value assignment services for in vitro diagnostic quality control and calibrator materials
/02	c/o Sysmex Europe SE Bornbarch 1 22848 Norderstedt Germany	Design and development, manufacture, distribution, service and administration
/03	c/o Sysmex Europe SE Bornbarch 3 22848 Norderstedt Germany	Technical service, service provision and design, development and manufacture of software for In vitro diagnostic use
/04	c/o Sysmex Europe SE Bornbarch 4 22848 Norderstedt Germany	Service and regulatory issues, design and development, technical product management
/05	c/o Sysmex Europe SE Bornbarch 5 22848 Norderstedt Germany	Provision of assay value assignment services for in vitro diagnostic quality control and calibrator materials
/06	c/o Sysmex Europe SE Bornbarch 8 22848 Norderstedt Germany	Distribution and service
/07	c/o Sysmex Europe SE Bornbarch 10 22848 Norderstedt Germany	Distribution, service, design and development
/08	c/o Sysmex Europe SE Mainstr. 7 24539 Neumünster Germany	Manufacture of in vitro diagnostic reagents

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Deelböge 19 D  
22297 Hamburg  
Germany

The scope of certification also covers the following sites:

/09	c/o Sysmex Europe SE Falkenried 88 20251 Hamburg Germany	Design, development and manufacture of in-vitro diagnostic tests used in the diagnosis, management and detection of cancer and genetic testing
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