

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**


Registration No.: SX 1348623-1  
Certificate Holder: Sysmex Inostics GmbH  
Falkenried 88  
20251 Hamburg  
Germany

Scope: Design and Development, Manufacture and Distribution of in-vitro diagnostic kits for testing acquired genetic or chromosomal alterations used in the management of cancer.

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.: 1156197-40  
Effective date: 2024-10-26  
Expiry date: 2027-10-25  
Issue date: 2024-09-27  
Replaces certificate SX 1348623-1 issued 2021-10-19

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

  
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