

# Certificate



**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 1348623-1

Organization: Sysmex Inostics GmbH  
Falkenried 88  
20251 Hamburg  
Germany

Scope: Design and Development, Manufacture and Distribution of nucleic acid in vitro diagnostic products including "Companion Diagnostics" 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.

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