

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Sysmex INOSTICS GmbH**  
**Falkenried 88**  
**20251 Hamburg**  
**Deutschland**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and Development, Manufacture and Distribution of  
molecular in-vitro diagnostic products including  
"Companion Diagnostics" used in the management of cancer**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-10-26  
Certificate Registration No.: SX 60132393 0001  
An audit was performed. Report No.: 21242760 005  
This Certificate is valid until: 2021-10-25

Certification Body



Date 2018-10-26



Dipl.-Ing. Sven Hoffmann

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