

# Certificate

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

Registration No.: SX 1170693-1

Organization: DRG Instruments GmbH  
Frauenbergstr. 18  
35039 Marburg  
Germany

Scope: Design and development, manufacture and distribution of in-vitro diagnostic test kits used in the diagnosis or detection of transmissible agents and sexually transmissible agents, cancer, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, compatibility testing, fertility testing, pregnancy testing, therapeutic drug monitoring and the

Design and development, installation and service of in-vitro diagnostic analyzers.

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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