

# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**DRG Instruments GmbH**  
**Frauenbergstr. 18**  
**35039 Marburg**  
**Deutschland**

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

**(see attachment for scope included)**

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: 2019-04-29  
Certificate Registration No.: SX 60138947 0001  
An audit was performed. Report No.: 21195407 014  
This Certificate is valid until: 2022-04-02

Certification Body



Date 2019-04-29



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60138947 0001  
**Report No.:** 21195407 014

**Organization:** DRG Instruments GmbH  
Frauenbergstr. 18  
35039 Marburg  
Deutschland

**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 and the

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

**Certification Body**



**Date:** 2019-04-29



*S. Hoffmann*  
**Dipl.-Ing. Sven Hoffmann**