

# Certificate

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

hereby certifies that the organization

**Healgen Scientific Limited  
Liability Company  
3818 Fuqua Street  
Houston, TX 77047  
USA**

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

**Design and Development, Manufacture and Distribution of  
In Vitro Diagnostic Reagents for Cardiac Diseases,  
Infectious Diseases, Oncology and for Biochemistry  
as well as Rapid Tests for Fertility and Drugs of Abuse**

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: 2019-03-01  
Certificate Registration No.: SX 60135029 0001  
An audit was performed. Report No.: 15090679 004  
This Certificate is valid until: 2022-02-28

Certification Body



Date 2018-12-29



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