

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



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety