



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Healgen Scientific Limited
 Liability Company
 3818 Fuqua Street
 Houston
 Texas
 77047
 USA

DUNS Number: 11-720-4761

Holds Certificate No:

MDSAP 713643

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test of Infectious Diseases, Drugs of Abuse, Fertility, Oncology and Biochemistry.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-12-11

Effective Date: 2019-12-11

Expiry Date: 2022-12-10



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 713643**

Location	Registered Activities
Zhejiang Orient Gene Biotech Co., Ltd. 3787 East Yangguang Avenue Dipu Street Anji Huzhou Zhejiang 313300 China DUNS Number: 42-114-8715	Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test of Infectious Diseases, Drugs of Abuse, Fertility, Oncology, and Biochemistry.
Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston Texas 77047 USA DUNS Number: 11-720-4761	Management Activities for Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test of Infectious Diseases, Drugs of Abuse, Fertility, Oncology and Biochemistry as a Legal Manufacturer and Warehouse Management.



Original Registration Date: 2019-12-11 Effective Date: 2019-12-11 Expiry Date: 2022-12-10

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.