

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

HTG Molecular Diagnostics, Inc.

3430 E. Global Loop
Tucson
Arizona
85706
USA

Holds Certificate Number:

FM 585907

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacturing, distribution of instruments, software, reagents and test kits used in the analysis of gene expression.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2012-07-27

Latest Revision Date: 2022-09-15

Effective Date: 2021-06-11

Expiry Date: 2024-06-10

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