

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Commonwealth Diagnostics International,
Inc.
39 Norman Street
Salem
Massachusetts
01970
USA

Holds Certificate Number:

MD 654462

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

Design, manufacture, repackage, relabel and distribution of in-vitro diagnostic specimen collection devices.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-06-09

Latest Revision Date: 2020-06-04

Effective Date: 2020-06-09

Expiry Date: 2023-06-08

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