

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, repackaging, relabel and distribution of in-vitro diagnostic specimen collection devices.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-06-09

Latest Revision Date: 2023-05-30

Effective Date: 2023-06-09

Expiry Date: 2026-06-08

Page: 1 of 1



...making excellence a habit.™