

# 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 breath specimen collection devices.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-06-09

Latest Revision Date: 2018-05-16

Effective Date: 2017-06-09

Expiry Date: 2020-06-08

Page: 1 of 1



003

...making excellence a habit.™