

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

AmericanBio, Inc.

20 Dan Road
Canton
Massachusetts
02021
USA

Holds Certificate Number:

FM 564956

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

Contract manufacture of reagent components of medical devices for diagnostics and life science research.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2011-02-17

Latest Revision Date: 2023-01-06

Effective Date: 2023-02-17

Expiry Date: 2026-02-16

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