

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Spear Bio, Inc.
100 Trade Center Dr.
Suite 510
Woburn
Massachusetts
01801
USA

Holds Certificate Number:

MD 782331

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

Design, development and manufacture of in vitro diagnostic reagents and test kits for the screening of infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-07-26

Latest Revision Date: 2023-07-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

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