

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Scimedx Corporation
53 Richboynton Road
Dover
New Jersey
07801
USA

Holds Certificate No:

FM 702592

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

The design/development, manufacture, service, distribution of in-vitro diagnostic medical device test kits used for the detection of antibodies present in vascular, infectious and autoimmune disease states.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-10-16

Latest Revision Date: 2021-08-31

Effective Date: 2021-09-06

Expiry Date: 2024-09-05

