

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Ohio Medical LLC
1111 Lakeside Drive
Gurnee
Illinois
60031
USA

Facility ID Number: F003109

Holds Certificate No:

MDSAP 701947

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture, distribution and servicing of vacuum regulators, portable suction equipment, flowmeters, medical hose assemblies, gas regulators, collection canisters, overflow safety trap assemblies, suction filters, and venturi suction adapters for the areas of suction and oxygen therapy.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-06-02

Effective Date: 2024-01-31

Expiry Date: 2027-01-30



BSI Group America Inc. is an MDSAP recognised auditing organization

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