

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

The Prometheus Group
One Washington Street, Suite #3171
Dover
New Hampshire
03820
USA

Facility ID Number: F003215

Holds Certificate No:

MDSAP 703987

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

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, manufacturer, and distributor of biofeedback, uroflowmetry systems, manometry systems, neuromuscular stimulators and ultrasound imaging systems for areas of orthopedics and urology

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-04-10

Effective Date: 2022-10-29

Expiry Date: 2025-10-28



BSI Group America Inc. is an MDSAP recognised auditing organization