

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BTT Health GmbH
Beurer Strasse 25a
86926 Greifenberg
Germany

Facility ID Number: F003248

Holds Certificate No:

MDSAP 703539

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

Design and Development, production, distribution and service of Ultrasound and mechanical vibration Therapy Devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-07-22

Effective Date: 2023-07-22

Expiry Date: 2026-07-21



BSI Group America Inc. is an MDSAP recognised auditing organization