MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final assessment report no.	Effective date	Expiry date
20634GB451260722	20634AU01F	2026-07-22	2029-06-25

This is to certify that

BTT Health GmbH

Beurer Str. 25a, 86926 Greifenberg, Germany

has introduced, applies and maintains a management system at the site(s) listed on the following page(s).

This management system has been audited and found to conform to the quality management systems standard

ISO 13485:2016 and the following country-specific requirements

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)
Brazil:	RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada:	Medical Devices Regulations (SOR 98/282) – Part 1 (applicable requirements)
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)
United States:	21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2026-07-22

For the issuing office
DNV MEDCERT GmbH
Brooktorkai 18, 20457 Hamburg, Germany

MDSAP
Medical Device Single Audit Program

Markus Bianchi
Certification Body Operations

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact medcert-info@dnv.com

Certificate no.: 20634GB451260722
Place and date: Hamburg, 2026-07-22

Activities and products/services covered by this certificate

Design and development, manufacturing, distribution, and servicing of

- Ultrasound and mechanical vibration therapy devices

Sites covered by this certificate and associated (partial) scopes

BTT Health GmbH, Beurer Str. 25a, 86926 Greifenberg, Germany
Facility ID: F009006

Design and development, manufacturing, distribution, and servicing of

- Ultrasound and mechanical vibration therapy devices

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