

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

ThermoTek Inc.

Main Site: 1200 Lakeside Parkway #200

Flower Mound, TX 75028, USA

(FIN F000984)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

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

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design, development, manufacturing, distribution and servicing of Thermal therapy systems and accessories, Compression therapy systems and accessories, Dermal cooling systems and accessories.

Certificate Number:

0079066-01

Initial Certification Date:

2018-08-02

Date of Certification Decision:

2021-07-30

Certification Effective Date:

2021-08-01

Certification Expiry Date:

2024-08-01



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

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