

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ThermoTek Inc.

Main Site: 1200 Lakeside Parkway, Building 2

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

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(excluding Part 1.6)

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:

0079066-02

Initial Certification Date:

2018-08-02

Date of Certification Decision:

2024-07-09

Certification Effective Date:

2024-08-01

Certification Expiry Date:

2027-08-01



intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
4700 Broadmoor SE, Suite 200
Kentwood, MI, USA, 49512

