

CERTIFICATE

Number: 3818845

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Gentherm Medical, LLC dba Cincinnati Sub -Zero Products, LLC

12011 Mosteller Road
Cincinnati, OH 45241
United States Of America

Manufacturer DUNS 004249462

Conforms to the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169 and Article 4 to Article 68
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

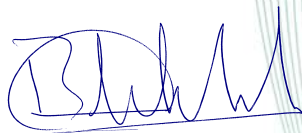
Scope:

The design, manufacture, distribution and service of devices for therapeutic treatment, measurement and control of patient temperature.

Certificate expiry date: **28 November 2020**
Certificate effective date: 10 February 2020
Certified since: 28 November 2017

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: **3818845**

The management system of the organization(s) and/or location(s) of:

Gentherm Medical, LLC dba Cincinnati Sub -Zero Products, LLC

**12011 Mosteller Road
Cincinnati, OH 45241
United States Of America**

Certified organization(s) and/or locations:

Different scope:

Warehousing and Delivery

Gentherm Medical, LLC
dba Cincinnati Sub-Zero Products, LLC
Honeymoon Paper Warehouse
7100 Dixie Highway
Fairfield, OH 45014
United States of America

Manufacturer DUNS 556879252

Addendum expiry date: **28 November 2020**

Addendum effective date: 10 February 2020