

# CERTIFICATE

Number: **3818845**

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

## Gentherm Medical LLC

12011 Mosteller Road  
Cincinnati, OH 45241  
United States of America

Manufacturer Facility Identifier F000605

Conforms with 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

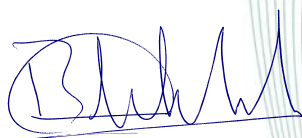
### Scope:

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

Certificate expiry date: **2021-11-28**  
Certificate effective date: 2021-04-23  
Certified since: 2017-11-28

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

12011 Mosteller Road  
Cincinnati, OH 45241  
United States of America

Certified organization(s) and/or locations:

Different scope

Gentherm Medical LLC  
7100 Dixie Highway  
Fairfield, OH 45014  
USA

Warehousing and Delivery

Addendum expiry date: **2021-11-28**

Addendum effective date: **2021-04-23**