

# 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.

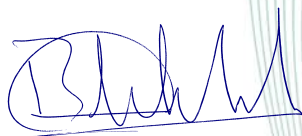
Certificate expiry date: 2026-11-28

Certificate effective date: 2024-1-10

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.M. McKenzie**  
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.



DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
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# 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  
Honeymoon Paper Warehouse  
7100 Dixie Highway  
Fairfield, OH 45014  
United States of America

Finished Goods Storage and Shipping

Addendum expiry date: 2026-11-28

Addendum effective date: 2024-1-10