



Certificate No. 10365-6-2019

CERTIFICATE OF EXPORTABILITY SECTION 801(e)(1)

The Food and Drug Administration certifies that the product(s) described below is subject to its jurisdiction under the Federal Food, Drug, and Cosmetics Act (the Act). The products described below may not be sold or offered for sale in the United States. The company has certified to the Food and Drug Administration that:

- * the product(s) accords to the specifications of the foreign purchaser;
- * the product(s) is not in conflict with the laws of the country to which it is intended for export;
- * the shipping package for the product(s) is labeled on the outside that it is intended for export;
and
- * the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 801(e)(1) of the Act.

Name of Product(s)

See Attached List
(One Page)

Name of Company, Address

Gentherm Medical, LLC
12011 MOSTELLER RD 3rd Floor
CINCINNATI, OH USA 45241

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 10, 2019 to June 09, 2021.





U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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Certificate of Exportability Section 801(e)(1) - Name of Product(s) Attachment Page 1 of 1

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12011 MOSTELLER RD
3rd Floor
CINCINNATI, OH USA 45241

Name of Product(s)

UV TREQ ADVANCED TEMPERATURE MANAGEMENT SYSTEM AND ACCESSORIES INCLUDING
BLANKETS
PlastiPad Reusable Blankets - Model 195N

-----END OF PRODUCT LIST-----

