



Certificate No. 7210-3-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CDR Cesar A. Perez, PhD, Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 27, 2019 to March 26, 2021.





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

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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

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

Name of Manufacturer

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

---END OF MANUFACTURER/DISTRIBUTOR LIST---





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

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

Name of Product(s)

Blanketrol III Model 233 Hyper/Hypothermia System and Accessories

*PlastiPad Reusable Blankets

(Models 193, 193CPC, 194, 194CPC, 195N, 196, 196CPC)

*Maxi-Therm Single Patient Use Blankets

(Models 273, 274, 276, 286)

*Maxi-Therm Lite Single Patient Use Blankets

(Models 300, 800, 801, 870, 871, 872, 873, 874, 875, 876, 879)

*Gelli-Roll Hyper/Hypothermia Blankets and Pads

(Models 193P, 194P, 195P, 286, 287)

*Kool-Kits

(Models 900, 910, 920, 930, 950)

*Cold Therapy Temp-Pads

(Models 600, 601)

CoolBlue Model 25-01 Hyper/Hypothermia System

Norm-O-Temp Model 111Z Hyperthermia System and Accessories

*PlastiPad Reusable Blankets

(Models 193, 193CPC, 194, 194CPC, 195N, 196, 196CPC)

*Maxi-Therm Single Patient Use Blankets

(Models 273, 274, 276, 286)

*Maxi-Therm Lite Single patient Use Blankets

(Models 300, 870, 871, 872, 873, 874, 876)

*Gelli-Roll Hyper/Hypothermia Blankets and Pads

(Models 193P, 194P, 195P, 286, 287)

Hemotherm Model 400CE Dual Reservoir: Cooler / Heater System and Accessories

*Hemotherm Remote control (Model 414CE)

*PlastiPad Reusable Blankets

(Models 193, 193CPC, 194, 194CPC, 195N, 196, 196CPC)

*Maxi-Therm Single Patient Use Blankets

(Models 273, 274, 276, 286)

*Maxi-Therm Lite Single patient Use Blankets

(Models 873, 874, 876)

*Gelli-Roll Hyper/Hypothermia Blankets and Pads

(Models 193P, 194P, 195P, 286, 287)

WarmAir Model 135 Convective Warming System and Accessories

*FilteredFlo Blankets

(Models 145, 243, 244, 246, 247, 248, 344, 442, 443, 460, 461, 462, 542)

Electri-Cool II Model 767 Localized Cold Therapy System and Accessories

*Maxi-Therm Single Patient Use Blankets (Model 273)

*Maxi-Therm Lite Single patient Use Blankets (Models 870, 871, 872, 873)

*PlastiPad Reusable Blankets (Model 193CPC)

*Gelli-Roll Hyper/Hypothermia Blankets and Pads (Model 193P)

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

