



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

Certificate No. 11501-6-2021

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

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 30, 2021 to June 29, 2023.





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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.
Cincinnati, OH
USA 45241

Name of Manufacturer

Gentherm Medical, LLC
Doing Business As
Cincinnati Sub-Zero Products, LLC
12011 MOSTELLER RD
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 Owner Operator

Genther Medical LLC
12011 MOSTELLER RD.
Cincinnati, OH
USA 45241

Name of Manufacturer

Genther Medical, LLC

Doing Business As

Cincinnati Sub-Zero Products, LLC
12011 MOSTELLER RD
Cincinnati, OH
USA 45241

Name of Product(s)

Norm-O-Temp Model 111Z Hyperthermia System and Accessories
Electri-Cool II Model 767 Localized Cold Therapy System and Accessories
WarmAir Model 135 Convective Warming System and Accessories
Blanketrol III Model 233 Hyper/Hypothermia System and Accessories
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
Maxi-Therm Lite Single Patient Use Blankets Models 300, 800, 801, 870, 871, 872, 873, 874, 876
Gelli-Roll Hyper/Hypothermia Blankets and Pads Models 193P, 194P, 195P
Kool-Kits Models 900, 910, 920, 930, 950
Cold Therapy Temp-Pads Models 600, 601
FilteredFlo Blankets Models 145, 243, 244, 246, 247, 248, 344, 442, 443, 460, 461, 462, 542
Reusable Hoses Model 186, 286, 287

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

