



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

Certificate No. 5368-1-2018

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.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from January 29, 2018 to January 28, 2020.





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

Name of Corporate Headquarters

Augustine Temperature Management, LLC
6581 CITY WEST PARKWAY
Eden Prairie, MN USA 55344

Name of Manufacturer

Augustine Temperature Management, LLC
7656 W. 78th St.
Minneapolis, MN USA 55439

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





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Name of Manufacturer

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Minneapolis, MN USA 55439

Name of Product(s)

HotDog Patient Warming Blankets
B103 Lower Body Warming Blanket
B104 Full Body Warming Blanket
B105 Multi Position Warming Blanket
B107 Head Warming Blanket
B108 Lower Body Warming Blanket, 70 x 100 cm
B110 Torso Blanket, V-Shaped
B203 Small Lower Body Blanket, 45 x 55 cm
B270 Head Warming Wrap, Pediatric, Small
B271 Head Warming Wrap, Pediatric, Large
HotDog Patient Warming Mattresses
U101 Underbody Warming Mattress, 50 x 81 cm
U102 Underbody Warming Mattress, 50 x 127 cm
U220 Underbody Warming Mattress, Pediatric
U300 Underbody Warming Mattress, Trendelenburg, 50 x 91 cm
HotDog Patient Warming System Controllers
WC01/WC02 HotDog Controller
WC01R/WC02R Hot Dog Controller - Refurbished
WC51/WC52 HotDog Multifunction Controller
WC51R/WC52R HotDog Multifunction Controller - Refurbished

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

