



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

CENTER FOR DEVICES AND RADILOGICAL HEALTH

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

**Certificate No. 8088-3-2018**

**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)**

IncuBlanket Infant Warming Blanket and Pack

**Name of Company, Address**

WARMILU LLC  
8186 JACKSON RD STE C  
Ann Arbor, MI USA 48103

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 March 22, 2018 to March 21, 2020.**

