



Certificate No. 14140-9-2022

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

Name of Manufacturer

HELMER Inc.
14400 Bergen Blvd
NOBLESVILLE, IN USA 46060

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 September 30, 2022 to September 29, 2024.





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 Product(s) Attachment Page 1 of 1

Name of Manufacturer

HELMER Inc.
14400 Bergen Blvd
NOBLESVILLE, IN
USA 46060

Name of Product(s)

DH2 Plasma Thawing System
DH4 Plasma Thawing System
DH8 Plasma Thawing System

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

