



Certificate No. CT:PKPR-HQVT

Application Number: 1814-22

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:

Helmer Inc, located at 14400 Bergen Boulevard, Noblesville, IN 46060, USA, manufactured the following product(s):

Product Name

PF15-PRO Agitator
PF48-PRO Agitator
PF96-PRO Agitator
PF96i Agitator
PF96h Agitator
PC100-PRO Incubator
PC900-PRO Incubator
PC1200-PRO Incubator
PC2200i Incubator
PC2200h Incubator
PC2200-PRO Incubator
PC3200i Incubator
PC3200h Incubator
PC3200-PRO Incubator
PC4200i Incubator
PC4200h Incubator
PC4200-PRO Incubator

The product(s) described above and the plant(s) where it is produced are subject to the jurisdiction of the FDA under the Federal, Food, Drug, and Cosmetic Act.

It is certified that the above listed 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 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.

Signature _____

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from October 18, 2022 to October 17, 2024.

