



Certificate No. CT:K3D7-C9R7

Application Number: 0518-20

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

Ultra CW II Automatic Cell Washing System

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 January 22, 2020 to January 21, 2022.

