



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

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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

Certificate No. CT:9A6S-YYB8

Application Number: 0905-22

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:

Immucor GTI Diagnostics, Inc, located at 20925 Crossroads Circle, Waukesha, WI 53186, USA, manufactured the following product(s):

Product Name
LIFECODES LSA Class I
LIFECODES LSA Class II
LIFECODES Class I ID
LIFECODES Class II IDv2
LIFECODES LifeScreen Deluxe
MATCH IT! Antibody
PakPlus
ThromboType1

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 March 30, 2022 to March 29, 2024.

