



**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:ZZYY-B9EB

Application Number: 0915-22

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 HLA-A SSO Typing Kit
LIFECODES HLA-A eRES SSO Typing Kit
LIFECODES HLA-B SSO Typing Kit
LIFECODES HLA-B eRES SSO Typing Kit
LIFECODES HLA-C eRES SSO Typing Kit
LIFECODES HLA-DRB1 SSO Typing Kit
LIFECODES HLA-DRB1 eRES SSO Typing Kit
LIFECODES HLA-DRB3,4,5 Typing Kit
LIFECODES HLA-DQA1/B1 SSO Typing Kit
LIFECODES HLA-DPA1/B1 SSO Typing Kit
MATCH IT! DNA Software

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 April 21, 2022 to April 20, 2024.

