



	CERTIFICATIONS	DOCUMENT #: 96011
	TITLE: Certificate of Foreign Government (CBER)	REVISION #: A
RANFAC CORP		PAGE: Cover page
		ISSUED/REVISED PER ECO #: 23287

WRITTEN/REVISED BY: Michaela McKinney (Dec 13, 2023 11:01 EST) DATE: Dec 13, 2023

REVIWED BY: Eric Kreuz (Dec 13, 2023 11:44 EST) DATE: Dec 13, 2023

REVISION RECORD

Previous ECOs:

Revision Number	ECO Number	Description of Changes
A	23287	Initial Release



Certificate No. CT:V4JX-Q2P6

Application Number: 1144-23

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:

Ranfac Corp., located at 30 Doherty Ave., Avon, MA 02322, USA, manufactured the following product(s):

Product Name
Platelet Separator Pack
CER-PRP-80
CER-PRP-40
CER-PRP-SINGLE
CER-PRP-TRIPLE-B
CER-PRP-DOUBLE
CER-PRP-SINGLE-B
CER-PRP-SINGLE-PB
CER-BKT
CER-PRP-CW
Adipose Separator Pack
CER-LP-40
CER-ASP

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 December 08, 2023 to December 07, 2025.










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Final Audit Report

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