



	CERTIFICATIONS	DOCUMENT #: 96003
	TITLE:  Ranfac Foreign Cert	REVISION #: E
RANFAC CORP		PAGE: Cover page
		ISSUED/REVISED PER ECO #: 23296

WRITTEN/REVISED BY: Michaela McKinney DATE: Dec 27, 2023  
Michaela McKinney (Dec 27, 2023 08:44 EST)

REVIWED BY: Eric Kreuz DATE: Dec 27, 2023  
Eric Kreuz (Dec 27, 2023 08:50 EST)

REVISION RECORD

Previous ECOs:

Revision Number	ECO Number	Description of Changes
A	18104	Release of Cert with Ranfac Numbering Scheme
B	19151	Renewal, July 2021
C	21776	Renewal, June 2023
D	22263	Renewal, September 2024
E	23296	Revision of CFG, removal of PRP.



**Certificate No. 3113-12-2023**

**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:

**Name of Product(s)**

See Attached List

(Two Pages)

**Name of Manufacturer/Distributor, Address**

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above 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 such 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.

Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from December 21, 2023 to December 20, 2025.**





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

**Certificate No. 3113-12-2023**

**Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1**

**Name of Corporate Headquarters**

Ranfac Corp.  
30 Doherty Ave.  
Avon, MA  
USA 02322

**Name of Manufacturer/Distributor**

Ranfac Corp.  
30 DOHERTY AVE  
Avon, MA  
USA 02322

---END OF MANUFACTURER/DISTRIBUTOR LIST---





**Certificate No. 3113-12-2023**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2**

**Name of Corporate Headquarters**

Ranfac Corp.  
30 Doherty Ave.  
Avon, MA  
USA 02322

**Name of Manufacturer/Distributor**

Ranfac Corp.  
30 DOHERTY AVE  
Avon, MA  
USA 02322

**Name of Product(s)**

Ranfac Bone Marrow Biopsy Needles

RBN-114

RBN-116

RBN-133

RBN-132

RBN-84

RBN-86

RBN-114S

RBN-116S

Ranfac "J" Bone Marrow Biopsy Needles

RJN-114

RJN-116

RJN-84

RJN-86

RJN-132

RJN-134

Ranfac "T" Bone Marrow Biopsy Needles

RTN-114

RTN-116

RTN-84

RTN-86

RTN-132

RTN-134

Ranfac Bone Marrow Aspiration Needles

RAN-11

RAN-1111

RAN-1115

RAN-11B

RAN-11D

RAN-11N

RAN-1111N

RAN-1115N

RAN-112N

RAN-113N

RAN-11125

RAN-810

RAN-815

RAN-86

RAN-825

RAN-8N

RAN-835N

RAN-10N

RAN-15N

RAN-3N

RAN-89N





**Certificate No. 3113-12-2023**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2**

RAN-1345

RAN-136N

RAN-1528

RAN-154

RAN-1628

Marrow Cellution Bone Marrow Aspiration Needle

MC-RAN-11C

MC-RAN-11CSTS

MC-RAN-8C

MC-RAN-8CSTS

MC-RAN-13C

MC-RAN-13A

MC-RAN-13FA

MC-RAN-13FAB

Ranfac Suture Graspers

RSG-14

RSG-14-13

RSG-14F-4

RSG-14F-C

RSG-14SP

RSG-14-102

Bone Marrow Aspiration

CER-ORTHO

CER-ORTHO-M

CER-EXT

CER-EXT-M

CER-LA

CER-LA-M

CER-FLEX

Bone Dowel Harvesting

CER-BN-116

CER-BN-84

Access/Delivery

CER-SUB-1560

CER-SUB-1111-OT

CER-SUB-1112-CT

CER-SUB-83N

CER-SUB-825

CER-SUB-825-M

-----END OF PRODUCT LIST-----










# 96003\_RevE\_Portfolio

Final Audit Report

2023-12-27

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