



Certificate No. 2892-12-2019

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:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
Body Composition Analyzer, I20; Body Composition Analyzer, I30	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 17, 2019 to December 16, 2021.





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

Name of Manufacturer

MEDIANA CO., LTD.
132, Donghwagongdan-ro, Munmak-eup
Wonju-si, Gangweondo KOREA, REPUBLIC OF 220-801

Name of Distributor

MEDIANA USA, INC.
2799 152ND AVE NE STE 7A
Redmond, WA USA 98052

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





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

DEC 17 2019

Jason Kim
General Manager
Mediana USA, Inc.
2799 152nd Ave NE #7A
Redmond, WA 98052

Dear Mr. Jason Kim:

This is in response to your Certificate to Foreign Government request. This Certificate to Foreign Government only attests to the status of your product under the Federal Food, Drug, and Cosmetic Act. You are responsible for assuring that your product, when exported to these countries, is in compliance with all other US laws and regulations regarding export of such products to these specific countries. Enclosed are the certificates that you requested. If you have any additional questions, please email CDRHCECATS@fda.hhs.gov or call (301) 796-7400, option 3.

Exports Team
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

Enclosure:

1 Certificate(s)
2892-12-2019