



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

Certificate No. CFG-NE318-5-2023

**CERTIFICATE TO FOREIGN GOVERNMENT
FOR DEVICE NOT EXPORTED FROM THE UNITED STATES**

The U.S. Food and Drug Administration (FDA) certifies the following information concerning the device(s) listed below to be shipped from SOUTH KOREA into foreign countries.

Name of Device(s)

See Attached List

(One Page)

Name of Manufacturer, Address

Manufacturer

P&S MECHANICS CO.,LTD
Rm 509, Woori Venture Town 2, 70 Seonyu-ro, Yeongdeungpo-Gu
Seoul, Seoul
KOREA, SOUTH 07294

The device(s) described above (and the manufacturing site(s) which produces it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

It is certified that the above device(s) may be marketed in the United States of America at this time. The manufacturing establishment(s) in which the device(s) is produced is subject to periodic inspections.

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 May 24, 2023 to May 23, 2025.

For more information about this certificate, please see the FDA's website
<<https://www.fda.gov/medical-devices/exporting-medical-devices/devices-not-exported-united-states>>

