



Certificate No. 9089-5-2019

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:

Name of Product(s)

See Attached List

(One Page)

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.

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 13, 2019 to May 12, 2021.





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

Name of Owner Operator

Nihon Kohden OrangeMed, Inc.
1800 E. Wilshire Avenue
Santa Ana, CA USA 92705

Name of Manufacturer

NIHON KOHDEN ORANGEMED, INC.
1800 E. Wilshire Avenue
Santa Ana, CA USA 92705

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





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

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Nihon Kohden OrangeMed, Inc.,
1800 E. Wilshire Avenue
Santa Ana, CA USA 92705

Name of Manufacturer

NIHON KOHDEN ORANGEMED, INC.
1800 E. Wilshire Avenue
Santa Ana, CA USA 92705

Name of Product(s)

Part Number	Device Name	Device Configuration
NKV-550-S	NKV-550 Series Ventilator System	NKV-550 Standard
NKV-550-U	NKV-550 Series Ventilator System	NKV-550 Universal
NKV-550-N	NKV-550 Series Ventilator System	NKV-550 Neonatal

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

