



Certificate No. 8885-5-2025-1

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

Name of Manufacturer

INTERNATIONAL MEDICAL DEVICES, INC
717 N Maple Dr
Beverly Hills, CA USA 90210

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 May 30, 2025 to May 29, 2027.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



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

Name of Manufacturer

INTERNATIONAL MEDICAL DEVICES, INC
717 N Maple Dr
Beverly Hills, CA
USA 90210

Name of Product(s)

Himplant/Penuma Pre-Formed Penile Silicone Block Implant,,Himplant/Penuma Pre-Formed Penile Silicone
Block Implant,
IMD006-L
IMD006-LLO
IMD006-XL
IMD006-XLO
IMD006-XXL
IMD009-L
IMD009-LLO
IMD009-XL
IMD009-XLO
IMD009-XXL

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

