



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

Certificate No. 12437-6-2018

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.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 29, 2018 to June 28, 2020.





**FDA U.S. FOOD & DRUG
ADMINISTRATION**

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

Name of Owner Operator

NEWMEDICAL TECHNOLOGY, INC.
310 Era Drive
Northbrook, IL USA 60062

Name of Manufacturer/Distributor

NEWMEDICAL TECHNOLOGY, INC.
310 Era Dr
NORTHBROOK, IL USA 60062

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





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

Name of Owner Operator

NEWMEDICAL TECHNOLOGY, INC.
310 Era Drive
Northbrook, IL USA 60062

Name of Manufacturer/Distributor

NEWMEDICAL TECHNOLOGY, INC.
310 Era Dr
NORTHBROOK, IL USA 60062

Name of Product(s)

NG-101 NewGel+ Beige Silicone Sheet, 5"x6" (12.7x15.2cm), 1 pc/package
NG-301 NewGel+ Clear Silicone Sheet, 5"x6" (12.7x15.2cm), 1 pc/package
NG-101S NewGel+ Beige Silicone Strips, 1"x6" (2.5x15.2cm), 4 pcs/package
NG-301S NewGel+ Clear Silicone Strips, 1"x6" (2.5x15.2cm), 4 pcs/package
NG-301S1 NewGel+ Clear Silicone Strip, 1"x6" (2.5x15.2cm), 1 pc/package
NG-301S2 NewGel+ Clear Silicone Strips, 1"x6" (2.5x15.2cm), 2 pcs/package
NG-30133 NewGel+ Clear Silicone Strips, 1"x3" (2.5x7.6cm), 3 pcs/package
NG-120 NewGel+ Beige Silicone Areola, 2 7/8" dia. (7.2cm dia.), 2 pcs/package
NG-320 NewGel+ Clear Silicone Areola, 2 7/8" dia. (7.2cm dia.), 2 pcs/package
NG-124 NewGel+ Beige Silicone Lollypop, 2 7/8"x6 1/2" (7.2x16.4cm), 2 pcs/package
NG-324 NewGel+ Clear Silicone Lollypop, 2 7/8"x6 1/2" (7.2x16.4cm), 2 pcs/package
NG-126 NewGel+ Beige Silicone Anchor, 10"x4 1/8" (25.4x10.5cm), 2 pcs/package
NG-326 NewGel+ Clear Silicone Anchor, 10"x4 1/8" (25.4x10.5cm), 2 pcs/package
NG-128 NewGel+ Beige Silicone Breast Kit, 2 pcs Areolas & 2 pcs Anchors/package
NG-328 NewGel+ Clear Silicone Breast Kit, 2 pcs Areolas & 2 pcs Anchors/package
NG-140 NewGel+ Beige Silicone Ear, (Left & Right), 3"x3" (7.5x7.5cm), 2 pcs/package
NG-340 NewGel+ Clear Silicone Ear, (Left & Right), 3"x3" (7.5x7.5cm), 2 pcs/package
NG-146 NewGel+ Beige Silicone Nose, 2 3/8"x2 3/4" (6.0x7.0cm), 2 pcs/package
NG-346 NewGel+ Clear Silicone Nose, 2 3/8"x2 3/4" (6.0x7.0cm), 2 pcs/package
NG-160 NewGel+ Beige Silicone Abdomen Sheet, 2"x8" (5.1x20.3cm), 2 pcs/package
NG-360 NewGel+ Clear Silicone Abdomen Sheet, 2"x8" (5.1x20.3cm), 2 pcs/package
NG-163 NewGel+ Beige Silicone Abdomen Sheet, 2"x18" (5.1x45.7cm), 1 pc/package
NG-363 NewGel+ Clear Silicone Abdomen Sheet, 2"x18" (5.1x45.7cm), 1 pc/package
NG-164 NewGel+ Beige Silicone Abdomen Sheet, 2"x24" (5.1x61.0cm), 1 pc/package
NG-364 NewGel+ Clear Silicone Abdomen Sheet, 2"x24" (5.1x61.0cm), 1 pc/package
NG-165 NewGel+ Beige Silicone Straight Sheet, 2"x8" (5.1x20.3cm), 1 pc/package
NG-365 NewGel+ Clear Silicone Straight Sheet, 2"x8" (5.1x20.3cm), 1 pc/package
NG-170 NewGel+ Beige Silicone Blanket, 10"x24" (25.4x61.0cm), 1 pc/package
NG-370 NewGel+ Clear Silicone Blanket, 10"x24" (25.4x61.0cm), 1 pc/package
NG-180 NewGel+ Beige Silicone Dots, 1" dia. (2.5cm dia.), 6 pcs/package
NG-380 NewGel+ Clear Silicone Dots, 1" dia. (2.5cm dia.), 6 pcs/package
NGO-800 NewGel+E Silicone Gel, 0.5 oz. (15 gram), 1 tube/package
NGO-810 NewGel+E Silicone Gel, 1.0 oz. (30 gram), 1 tube/package
NGO-892 NewGel+E Silicone Gel, 0.07 oz. (2 gram), 1 packette
8015 NewGel+E UV Silicone Gel, 0.5 oz. (15 gram), 1 tube/package
8030 NewGel+E UV Silicone Gel, 1.0 oz. (30 gram), 1 tube/package
NG-900 NewGel+ Silicone Belly Button, 0.54" dia. (1.4cm dia.), 1 pc/package
4001 NewGel+ REFRESH, Foaming Cleanser for Silicone Gel Sheeting, 1.69 fl.oz. (50 mL), 1 pc
1010303 DevraSorb Non-Adhesive Pad, 3"x3" (7.6x7.6cm), 10 pcs per box/5 boxes per case
1010404 DevraSorb Non-Adhesive Pad, 4"x4" (10x10cm), 10 pcs per box/5 boxes per case
1010405 DevraSorb Non-Adhesive Pad, 4"x4.5" (10x11.4cm), 10 pcs per box/5 boxes per case
1010413 DevraSorb Non-Adhesive Pad, 4"x13" (10x33cm), 10 pcs per box/5 boxes per case
1010506 DevraSorb Non-Adhesive Pad, 6"x6" (15.2x15.2cm), 10 pcs per box/5 boxes per case
1022525 DevraSorb Adhesive Island, 2"x2.5" (5x6.3cm) Pad on 4"x4" (10x10cm) Adhesive, 10 pcs per box/5 boxes per case
1024545 DevraSorb Adhesive Island, 4"x4.5" (10x11.4cm) Pad on 6"x6" (15.2x15.2cm) Adhesive, 10 pcs per box/5 boxes per case





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

2010405 DevraSorb Ultra Non-Adhesive Pad, 4"x4.5" (10x11.4cm), 10 pcs per box/5 boxes per case

2010606 DevraSorb Ultra Non-Adhesive Pad, 6"x6" (15.2x15.2cm), 10 pcs per box/5 boxes per case

3010108 DevraSorb Prime Non-Adhesive Pad, 1"x8" (2.5x20.3cm), 10 pcs per box/5 boxes per case

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

