



Certificate No. 15445-9-2017

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.

Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from October 06, 2017 to October 05, 2019.





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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

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

Name of Manufacturer

ASEPTICO, INC.
8333 216th St SE
WOODINVILLE, WA USA 98072

Name of Distributor

ASEPTICO, INC.
8333 216th St SE
WOODINVILLE, WA USA 98072

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





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Name of Distributor

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Name of Product(s)

AA-04SD SOAP DISPENSER & AA-04EXS EXTENSION SPOUT
AA-05A FOLDING EXTENSION ARM
AA-12A INSTRUMENT HOLDER ARM FOR ADU-12
AA-12HVE HIGH VOLUME TIP ADAPTER FOR ADU-12
AA-19A (FAMILY) HANDPIECE ILLUMINATION SYSTEMS
AA-20, AA-21, AA-25 (FAMILY) PORTABLE VACUUM SYSTEMS
AA-26 (FAMILY) DRY ORAL CUPS
AA-50, AA-51 REPLACEMENT TRAYS
AA-100 (FAMILY) AIR COMPRESSORS
ADC-01 (FAMILY) DENTAL CHAIR
ADC-02 (FAMILY) DENTAL CHAIR
ADC-08 (FAMILY) OPERATOR STOOL
ADC-09 ADVANCED PORTABLE OPERATOR STOOL
ADC-10 ADVANCED PORTABLE OPERATOR STOOL
ADU-01C SUPPLY CASE
ADU-04 PORTABLE DELIVERY SYSTEM
ADU-07 (FAMILY) ECONO AIR SYSTEM
ADU-10, 12, 17, 20, 22 PORTABLE DENTAL CARTS
ADU-40CF, 42CF PORTABLE FIELD SINK, AA-04CF LEG BRACE KIT,
AE-10, AE-20 (FAMILY), AE-23 (FAMILY), AE-26, AE-27, AE-20Y TUBING SETS
AE-14 (FAMILY), AE-18 (FAMILY), AE-19, AE-7 (FAMILY) & AE-70V FOOT SWITCHES
AE-4B-10 & AE-4B-30, AE-200-30, AE-205-30, AE-210-30, AE-225-30 & AE-230M-40 ELECTRIC
MICROMOTOR
AE-60 ELECTRIC TO PNEUMATIC FOOT SWITCH CONVERSION KIT
AE-8B WATER CLIP SET FOR AHP-64
AEU-03, AEU-08, AEU-10, AEU-12, AEU-16 (FAMILIES)
AEU-16C ELECTRIC DENTAL LAB UNIT
AEU-17 (FAMILY)
AEU-20 (FAMILY) ENDODONTIC SYSTEM
AEU-25 (FAMILY) ENDODONTIC SYSTEM
AEU-26 (FAMILY) IMPLANT & ORAL SURGERY MOTOR
AEU-27 (FAMILY) ELECTRONIC ENDODONTIC SYSTEM
AEU-28 (FAMILY) ENDODONTIC MOTOR SYSTEM
AEU-425 (FAMILY) PORTABLE DENTAL DELIVERY SYSTEM
AEU-525 (FAMILY) PORTABLE DENTAL DELIVERY SYSTEM
AEU-707 (FAMILY) IMPLANTOLOGY SYSTEM
AEU-1000 AND AEU-1070 (FAMILY) IMPLANT SURGERY SYSTEM TOUCH SCREEN
AEU-5000 ELECTRIC OPERATIVE MOTOR
AEU-6000 (FAMILY) IMPLANT, ENDO, ORAL SURGERY MOTOR
AEU-7000 (FAMILY) DENTAL SURGERY SYSTEMS
AEU-6B HOT SPOT GUTTA PERCHA WARMER
AEU-7 & AEU-70 PERISTALTIC WATER PUMPS
AHP-03, 04, 07 (FAMILY), TUBING & CLIP SETS
AHP-09 ASEPTISPRAY & AHP-09N NOZZLE
AHP-101 STRAIGHT ANGLE E-TYPE
AI-10 CROWN REMOVERS
AI-50 CROWN PLACER/REMOVER & AI-51 CROWN PLACER CUSHIONS





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ALU-27 DIRECT-A-BEAM LIGHT
ALU-29 ASEPTILIGHT, ALU-29CF COMMAND AIR PORTABLE LIGHT
ALU-40LED PORTABLE LIGHT
AMA-09 (FAMILY) TECHNIQUE KIT AND REFILL SETS
AMA-09B INSTRUMENT
AMA-09C BONDING AGENT - LIQUID + POWDER
AMC-20 MOBILE DENTAL CART
AMC-25 MOBILE DENTAL CART
ASC-04, 10 ELECTRIC DENTAL SCALER SYSTEM
ATC-01, 02, 03, 04, 06, 08, 09, 12 (FAMILY) TRAY CARTS
BA-8 BUR BLOCK
EHP-40 (FAMILY) SM ELECTRIC HEATED PLUGGER
EHP-50 (FAMILY) MED ELECTRIC HEATED PLUGGER
EHP-60 (FAMILY) LARGE ELECTRIC HEATED PLUGGER
EHP-TR (FAMILY) THERMAL RESPONSE TIP
FUE-100 ATERA FUE SYSTEM
GP-018E20 GUTTA PERCHA CARTRIDGE PACK (FAMILY)
GP-025SP GUTTA PERCHA CARTRIDGE PACK (FAMILY)
GP-035SP GUTTA PERCHA CARTRIDGE PACK (FAMILY)
I-13, I-14, I-18, I-19 RUBBER DAM FORCEPS AND PUNCHES
I-16, 17 RUBBER DAM FRAMES
I-70 PRE-FRAMED RUBBER DAMS (FAMILY)
I-70K HANDIDAM KIT
K-00 THRU K-212 CLAMPS
KB-08, 12, 18 STAINLESS STEEL CLAMP BOARDS
K-G1, G2 GUAZE CLAMPS
NWS-6, 7, 8 SELF-CONTAINED CLEAN WATER SYSTEMS
TA-1 SYRINGE TIPS
TA-90 (FAMILY), 95, 97 3-WAY SYRINGES
-----END OF PRODUCT LIST-----

