



**Certificate No. 11938-7-2020**

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.

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 July 22, 2020 to July 21, 2022.**





**Certificate No. 11938-7-2020**

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

**Name of Owner Operator**

ASEPTICO, INC.  
8333 216TH ST., S.E.  
Woodinville, WA USA 98072

**Name of Manufacturer**

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

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





**Certificate No. 11938-7-2020**

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

**Name of Owner Operator**

ASEPTICO, INC.  
8333 216TH ST., S.E.  
Woodinville, WA USA 98072

**Name of Manufacturer**

**Manufacturer**

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

**Name of Product(s)**

AA-04CF KIT LEG ADU-40CF BASE ASSY  
AA-04SD SOAP DISPENSER AND AA-04EXS EXTENSION SPOUT  
AA-04TSK KIT AND ADU-40CF TILT SWITCH  
AA-05A FOLDING EXTENSION ARM  
AA-100 (FAMILY) AIR COMPRESSOR  
AA-12A INSTRUMENT HOLDER ARM FOR ADU-12  
AA-12HVE HIGH VOLUME TIP ADAPTER FOR ADU-12  
AA-17AMAL AMALGAM SEPARATOR ADU-17 PORTABLE  
AA-19A (FAMILY) HANDPIECE ILLUMINATION SYSTEMS  
AA-20AMAL-CK AMALGAM SEPARATOR AMC-20 CART KIT  
AA-21, AA-25 (FAMILIES) PORTABLE VACUUM SYSTEMS  
AA-26 (FAMILY) DRY ORAL CUP  
AA-29, AA-290CK, AA-290VS SOLIDS COLLECTOR DISPOSABLE SCREEN  
AA-50, AA-51 REPLACEMENT TRAY  
AA-525AMAL AMALGAM SEPARATOR AEU-525 PORTABLE  
AA-UAMAL UNIVERSAL AMALGAM SEPARATOR  
ADC-01 (FAMILY) DENTAL CHAIR  
ADC-02 (FAMILY) DENTAL CHAIR  
ADC-08 (FAMILY) OPERATOR STOOL  
ADC-09 (FAMILY) ADVANCED PORTABLE OPERATOR STOOL  
ADC-10 (FAMILY) ADVANCED PORTABLE OPERATOR STOOL  
ADU-03 (FAMILY) ONE HPCE MINICONTROL  
ADU-04 (FAMILY) PORTABLE DELIVERY SYSTEM  
ADU-07 (FAMILY) ECONO AIR SYSTEM  
ADU-10, ADU-12, ADU-20, ADU-22, ADU-25 (FAMILIES) PORTABLE DENTAL CART  
ADU-17 (FAMILY) EXPRESS/EXPRESS II PORTABLE UNIT  
ADU-40CF, ADU-42CF PORTABLE FIELD SINK  
AE-10, AE-20, AE-23, AE-24, AE-26, AE-27 (FAMILIES) TUBING SET  
AE-14 (FAMILY), AE-18 (FAMILY), AE-19 FOOT SWITCH  
AE-4B-10, AE-4B-30, AE-210-30, AE-225-30, AE-230-40, AE-240-40, AE-250-30 (FAMILIES) ELECTRIC MICROMOTOR  
AE-60 ELECTRIC TO PNEUMATIC FOOT SWITCH CONVERSION KIT  
AE-70V (FAMILY), AE-70V2 (FAMILY) MULTIFUNCTION FOOT CONTROL  
AEU-03, AEU-08, AEU-10, AEU-12, AEU-16 (FAMILIES) ELECTRIC DENTAL LAB MOTOR  
AEU-1000 (FAMILY) AND AEU-1070 (FAMILY) IMPLANT SURGERY SYSTEM TOUCH SCREEN  
AEU-17 (FAMILY) SURGIMOTOR SYSTEM  
AEU-20 (FAMILY) ENDODONTIC SYSTEM  
AEU-25 (FAMILY) ENDODONTIC SYSTEM  
AEU-26 (FAMILY) IMPLANT AND ORAL SURGERY MOTOR  
AEU-27 (FAMILY) ELECTRONIC ENDODONTIC SYSTEM  
AEU-28 (FAMILY) ENDODONTIC MOTOR SYSTEM  
AEU-55 BEEFILL 2 IN 1  
BEEFILL CARTRIDGES 20 G=0. 8MM  
BEEFILL CARTRIDGES 23 G=0. 6MM  
BEEFILL CARTRIDGES 25 G=0. 45MM  
PLUGGER ISO 40/03 STD





**Certificate No. 11938-7-2020**

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

PLUGGER ISO 50/05 SOFT  
PLUGGER ISO 60/06 SOFT  
THERMAL RESPONSE TIP  
AEU-525 (FAMILY) PORTABLE DENTAL DELIVERY 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  
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  
ALU-40LED PORTABLE LIGHT  
AMA-09 (FAMILY) TECHNIQUE KIT AND REFILL SETS  
AMC-15 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-----

