



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

**Certificate No. 9555-6-2025-1**

**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

(Six 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 June 20, 2025 to June 19, 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](http://www.access.fda.gov/fecv/CDRH).



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

**Manufactured for Owner Operator**

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

**Name of Manufacturer**

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

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





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**Name of Manufacturer**

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

**Name of Product(s)**

AA-100-110 -COMPRESSOR AIRPAC III 110V - Unit, operative dental  
AA-100-220 - COMPRESSOR AIRPAC III 220V - Unit, operative dental  
AA-12CSB - BRKT ADU-12 CASE LID STANDOFF BRACKET KIT - Unit, operative dental  
AA-12HVE - ADAPTER HVE ADU-12 TASKFORCE - Unit, operative dental  
AA-20 - VACUUM RECHARGEABLE PORTABLE - Unit, operative dental  
AA-20A - AUXILIARY ARM MOBILE DENTAL CART SYSTEM AMC-20 / AMC-25 - Unit, operative dental  
AA-21ST - VACUUM HIGH VOLUME AVS INSTALLED ON ADU-04ST - Unit, operative dental  
AA-25ST - VACUUM SALIVA EJECTOR FOR USE ON ADU-04ST - Unit, operative dental  
AA-26SS - COLLECTOR DRY ORAL CUP STAINLS STEEL W/ STRAINER - Unit, operative dental  
AA-525AMAL - AMALGAM SEPARATOR AEU-525 PORTABLE - Unit, operative dental  
AA-96EXT - AIR EXTENSION LINE 25FT - Unit, operative dental  
ADC-01 -ASEPTICHAIR WITH CASE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-01-BLU - ASEPTICHAIR BLUE WITH CASE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-01CS -ASEPTICHAIR WITH CASE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-01P-RED - ASEPTICHAIR RED PEDO WITH CASE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-01-RED - ASEPTICHAIR RED WITH CASE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-02 - ADVANCED PORTABLE CHAIR - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-02-BLU - ADVANCED PORTABLE CHAIR BLUE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-02CF - MILITARY PORTABLE CHAIR - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-08 - ASEPTISTOOL PORTABLE OPERATOR STOOL - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-08-BLU - ASEPTISTOOL PORTABLE OPERATOR STOOL BLUE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-08CF - COMMAND FIELD PORTABLE OPERATOR STOOLS 6520-01-456-5406 - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-08-RED - ASEPTISTOOL PORTABLE OPERATOR STOOL - RED - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-08S - ASEPTISTOOL MILITARY SINGLE SOFT CASE NSN 6520-01-456-5467 - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-09CF - COMMAND FIELD ADVANCED MIL OPERATOR STOOLS - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-09S - COMMAND FIELD ADVANCED MIL OPERATOR STOOL SOFT CASE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-10 - ADVANCED PORTABLE OPERATOR STOOL - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-10-BLU - ADVANCED PORTABLE OPERATOR STOOL BLUE - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADC-10-RED - ASEPTISTOOL RED PORTABLE OPERATOR STOOL - CHAIR, DENTAL, WITHOUT OPERATIVE UNIT  
ADU-01C - CASE PORTABLE SUPPLY 5 DRAWER - Unit, operative dental  
ADU-03ST - THREE WAY AIR-WATER SYRINGE W/ STAND - Unit, operative dental  
ADU-04 - TWO HPCE MINI CONTROL - Unit, operative dental  
ADU-04ST - TWO HPCE MINI CONTROL W/ STAND - Unit, operative dental  
ADU-07 - HPCE CONTROL MANUAL SYSTEM - Unit, operative dental  
ADU-07A - HPCE CONTROL AUTOMATIC SYSTEM ECONOMY - Unit, operative dental  
ADU-12DCE - ASEPTICO TASK FORCE DELUXE - Unit, operative dental  
ADU-17A - EXPRESS AIR PORTABLE UNIT - Unit, operative dental





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ADU-17A2 - EXPRESS AIR 2 PORTABLE UNIT - Unit, operative dental  
ADU-17X - EXPRESS II PORTABLE UNIT - Unit, operative dental  
ADU-17X2 - EXPRESS PLUS II PORTABLE UNIT - Unit, operative dental  
ADU-20B - COMPRICART II - Unit, operative dental  
ADU-22 - PORTACART ECONOMY CART - Unit, operative dental  
ADU-25 - ENDO-CART BASE MODEL - Unit, operative dental  
AE-10 - TUBING LRG 5FT/MIN FOR AE-20 SILICONE .062ID X .125OD - Handpiece, direct drive, ac-powered  
AE-2 - FTN BARB 1/16 Y PLASTIC - Handpiece, direct drive, ac-powered  
AE-2 - FTN BARB 1/16 Y PLASTIC - Handpiece, direct drive, ac-powered  
AE-20 - TUBING PUMP SET ASEPTICO - Handpiece, direct drive, ac-powered  
AE-200-30 - MOTOR/CABLE ASSY W/LIGHT & H2O - Unit, operative dental  
AE-205-30EXT - MOTOR/CABLE ASSY 30K EXTERNAL WATER - Unit, operative dental  
AE-20Y - TUBING PUMP SET AEU-707Y YOSHIDA - Handpiece, direct drive, ac-powered  
AE-225-30 - MOTOR/CABLE ASSY AE-225-30 - Handpiece, direct drive, ac-powered  
AE-225-30MMT - MOTOR/CABLE ASSY W/EXTENDED CABLE AE-225-30MMT - Handpiece, direct drive, ac-powered  
AE-23 - TUBING SET AEU-7000 BAG - Handpiece, direct drive, ac-powered  
AE-230A-40 - MOTOR/CABLE ASSY AE-230A-40 - Handpiece, direct drive, ac-powered  
AE-230A-40 - MOTOR/CABLE ASSY AE-230A-40 - Handpiece, direct drive, ac-powered  
AE-230L-40 - MOTOR/CABLE ASSY AE-230 LED LIGHTED - Handpiece, direct drive, ac-powered  
AE-230L-40 - MOTOR/CABLE ASSY AE-230 LED LIGHTED - Handpiece, direct drive, ac-powered  
AE-230L-40EXT - MOTOR/CABLE ASSY AE-230L-40EXT LED LIGHTED W/10 FT CABLE - Handpiece, direct drive, ac-powered  
AE-230L-40EXT - MOTOR/CABLE ASSY AE-230L-40EXT LED LIGHTED W/10 FT CABLE - Handpiece, direct drive, ac-powered  
AE-230M-40 - MOTOR/CABLE ASSY AE-230M-40 - Handpiece, direct drive, ac-powered  
AE-230M-40 - MOTOR/CABLE ASSY AE-230M-40 - Handpiece, direct drive, ac-powered  
AE-230M-40EXT - MOTOR/CABLE ASSY AE-230M-40EXT W/10 FT CABLE - Handpiece, direct drive, ac-powered  
AE-230M-40EXT - MOTOR/CABLE ASSY AE-230M-40EXT W/10 FT CABLE - Handpiece, direct drive, ac-powered  
AE-23-10 - TUBING SET 10 FT AEU-7000 BAG - Handpiece, direct drive, ac-powered  
AE-23-10 - TUBING SET 10 FT AEU-7000 BAG - Handpiece, direct drive, ac-powered  
AE-23-BOT - TUBING SET AEU-7000 BOTTLE - Handpiece, direct drive, ac-powered  
AE-23-PUMP - TUBING SET PUMP SECTION - Handpiece, direct drive, ac-powered  
AE-23-PUMP - TUBING SET PUMP SECTION - Handpiece, direct drive, ac-powered  
AE-24 - TUBING SET AEU-1000 BAG - Handpiece, direct drive, ac-powered  
AE-24 - TUBING SET AEU-1000 BAG - Handpiece, direct drive, ac-powered  
AE-240-40 - MOTOR/CABLE ASSY AE-240-40 - Handpiece, direct drive, ac-powered  
AE-240SC-40 - MOTOR/CABLE ASSY AE-240SC-40 W/SHORT CABLE - Unit, operative dental  
AE-24-BOT - TUBING SET AEU-1000 BOTTLE - Handpiece, direct drive, ac-powered  
AE-24-BOT - TUBING SET AEU-1000 BOTTLE - Handpiece, direct drive, ac-powered  
AE-24-PUMP - TUBING SET PUMP SECTION AEU-1000 - Handpiece, direct drive, ac-powered  
AE-24-PUMP - TUBING SET PUMP SECTION AEU-1000 - Handpiece, direct drive, ac-powered  
AE-250-30 - MOTOR/CABLE ASSY AE-250-30 - Handpiece, direct drive, ac-powered  
AE-250-30-T - MOTOR/CABLE ASSY AE-250-30-T - Handpiece, direct drive, ac-powered  
AE-250F-30 - MOTOR/CABLE ASSY AE-250F-30 - Handpiece, direct drive, ac-powered  
AE-250-KER - MOTOR/CABLE ASSY AE-250-KER - Handpiece, direct drive, ac-powered  
AE-250-SYB - MOTOR/CABLE ASSY AE-250-SYB - Handpiece, direct drive, ac-powered  
AE-2MB - FTN MONT BLANC STNLS STEEL Y - Handpiece, direct drive, ac-powered  
AE-3 - FTN BARB 1/16 CONNECTOR PLTD - Handpiece, direct drive, ac-powered  
AE-3 - FTN BARB 1/16 CONNECTOR PLTD - Handpiece, direct drive, ac-powered  
AE-4B-10 - MOTOR/CABLE ASSY AE-4B 10K - Handpiece, direct drive, ac-powered  
AE-4B-30 - MOTOR/CABLE ASSY AE-4B 30K - Handpiece, direct drive, ac-powered  
AE-5M1 - HOLDER HNDPCE CRADLE M1 - Handpiece, direct drive, ac-powered  
AE-70V2 - FOOTSWITCH VARIABLE IMPLANT V2 - Handpiece, direct drive, ac-powered  
AE-70V2 - FOOTSWITCH VARIABLE IMPLANT V2 - Handpiece, direct drive, ac-powered  
AE-70V2-10 - FOOTSWITCH VARIABLE IMPLANT V2 W/10FT CABLE - Handpiece, direct drive, ac-powered





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AE-70V2-10 - FOOTSWITCH VARIABLE IMPLANT V2 W/10FT CABLE - Handpiece, direct drive, ac-powered  
AE-70V2BSB - FOOTSWITCH VARIABLE IMPLANT V2 BLUE SKY BIO - Handpiece, direct drive, ac-powered  
AE-70V2BSB - FOOTSWITCH VARIABLE IMPLANT V2 BLUE SKY BIO - Handpiece, direct drive, ac-powered  
AE-70V2-GLI - FOOTSWITCH VARIABLE IMPLANT V2 GLIDEWELL - Handpiece, direct drive, ac-powered  
AE-70V2-GLI - FOOTSWITCH VARIABLE IMPLANT V2 GLIDEWELL - Handpiece, direct drive, ac-powered  
AE-70V2MG-10 - FOOTSWITCH VARIABLE IMPLANT V2 MEGAGEN W/10FT CABLE - Handpiece, direct drive, ac-powered  
AE-70V2MG-10 - FOOTSWITCH VARIABLE IMPLANT V2 MEGAGEN W/10FT CABLE - Handpiece, direct drive, ac-powered  
AE-70V2SFI - FOOTSWITCH VARIABLE IMPLANT V2 SFI - Handpiece, direct drive, ac-powered  
AE-70V2SWM - FOOTSWITCH VARIABLE IMPLANT V2 SWM - Handpiece, direct drive, ac-powered  
AE-70V2SWM - FOOTSWITCH VARIABLE IMPLANT V2 SWM - Handpiece, direct drive, ac-powered  
AE-7A-10 - FOOTSWITCH ON/OFF W/8PIN 10FT - Handpiece, direct drive, ac-powered  
AE-7P - FOOTSWITCH ON/OFF 8 PIN - Handpiece, direct drive, ac-powered  
AE-7P-10 - FOOTSWITCH ON/OFF 8 PIN - 10FT - Handpiece, direct drive, ac-powered  
AE-7PM - FOOTSWITCH ON/OFF 4 PIN MALE - Handpiece, direct drive, ac-powered  
AE-7PM - FOOTSWITCH ON/OFF 4 PIN MALE - Handpiece, direct drive, ac-powered  
AE-7PM-10 - FOOTSWITCH ON/OFF 4 PIN MALE 10 FT - Handpiece, direct drive, ac-powered  
AE-7PMD - FOOTSWITCH ON/OFF DUAL 4 PIN MALE - Handpiece, direct drive, ac-powered  
AE-7PM-KER - FOOTSWITCH ON/OFF 4 PIN MALE 28 KERR - Handpiece, direct drive, ac-powered  
AE-7PM-SYB28 - FOOTSWITCH ON/OFF 4 PIN MALE 28 SYBRON - Handpiece, direct drive, ac-powered  
AE-7PM-T - FOOTSWITCH ON/OFF 4 PIN MALE TULSA DENTAL SPECIALTIES - Handpiece, direct drive, ac-powered  
AEU-1000 - IMPLANT SURGERY SYSTEM TOUCH SCREEN - Handpiece, direct drive, ac-powered  
AEU-1000 - IMPLANT SURGERY SYSTEM TOUCH SCREEN - Handpiece, direct drive, ac-powered  
AEU-1000, AEU-1000-70V DENTAL IMPLANT MOTOR SYSTEM 50 NCM - Handpiece, direct drive, ac-powered  
AEU-1000, AEU-1000-70V DENTAL IMPLANT MOTOR SYSTEM 50 NCM - Handpiece, direct drive, ac-powered  
AEU-1000-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1000-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1000BSB-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN BSB W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1000-IVS-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN IVS W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1000-OCO - IMPLANT SURGERY SYSTEM TOUCH SCREEN OCO - Handpiece, direct drive, ac-powered  
AEU-1000-OCO - IMPLANT SURGERY SYSTEM TOUCH SCREEN OCO - Handpiece, direct drive, ac-powered  
AEU-1070 - IMPLANT SURGERY SYSTEM TOUCH SCREEN 70NCM W/AE-7PM FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1070 - IMPLANT SURGERY SYSTEM TOUCH SCREEN 70NCM W/AE-7PM FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1070, AEU-1070-70V DENTAL IMPLANT MOTOR SYSTEM 70 NCM - Handpiece, direct drive, ac-powered  
AEU-1070, AEU-1070-70V DENTAL IMPLANT MOTOR SYSTEM 70 NCM - Handpiece, direct drive, ac-powered  
AEU-1070-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN 70NCM W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1070-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN 70NCM W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1070PTP-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN 70NCM PTP W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-1070PTP-70V - IMPLANT SURGERY SYSTEM TOUCH SCREEN 70NCM PTP W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-14 FAMILY - Unit, operative dental  
AEU-17 FAMILY - Handpiece, direct drive, ac-powered  
AEU-20 - ASEPTICO UNIT W/ TORQUE-110V SOLD WITH AE-4B-10 - Handpiece, direct drive, ac-powered  
AEU-20 FAMILY - Handpiece, direct drive, ac-powered







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AEU-25 - ASEPTICO ENDO UNIT \*\*INCL AE-4B-30 - Handpiece, direct drive, ac-powered  
AEU-25 FAMILY - Handpiece, direct drive, ac-powered  
AEU-25FP-T - FIELD PROGRAMER FOR AEU-25T (AEU25PGM) - Handpiece, direct drive, ac-powered  
AEU-25ITL - ENDO UNIT SWEDEN & MARTINA S.p.A. - Handpiece, direct drive, ac-powered  
AEU-25SSW - SSWHITE ENDO UNIT - Handpiece, direct drive, ac-powered  
AEU-25T - TULSA DENTAL ENDO UNIT \*\*INCL AE-4B-30 - Handpiece, direct drive, ac-powered  
AEU-26BIC - IMPLANT SYSTEM BICON - Handpiece, direct drive, ac-powered  
AEU-26L - Handpiece, direct drive, ac-powered  
AEU-26MMT - MOTOR SYSTEM MMT - Handpiece, direct drive, ac-powered  
AEU-26OS - IMPLANT SYSTEM ASEPTICO - Handpiece, direct drive, ac-powered  
AEU-27A - ASEPTICO ENDODONTIC SYSTEM - Handpiece, direct drive, ac-powered  
AEU-27T - ENDODONTIC SYSTEM AEU-27T - Handpiece, direct drive, ac-powered  
AEU-350 - ASEPTICO GO ULTRA PORTABLE DENTAL SYSTEM - Handpiece, direct drive, ac-powered  
AEU-350 - ASEPTICO GO ULTRA PORTABLE DENTAL SYSTEM - unit, operative dental  
AEU-350S - ASEPTICO GO ULTRA PORTABLE DENTAL SYSTEM W/Scaler - unit, operative dental  
AEU-5000 - OPERATIVE DENTAL SYSTEM - Handpiece, direct drive, ac-powered  
AEU-525 - TRANSPORT III PORTABLE DUAL VOLT UNIT 110/220V - Unit, operative dental  
AEU-525 - TRANSPORT III PORTABLE DUAL VOLT UNIT 110/220V - unit, operative dental  
AEU-525 FAMILY - Handpiece, direct drive, ac-powered  
AEU-525CF - TRANSPORT III COMMAND FIELD DUAL VOLTAGE UNIT 110/220V - Unit, operative dental  
AEU-525CF - TRANSPORT III COMMAND FIELD DUAL VOLTAGE UNIT 110/220V - unit, operative dental  
AEU-525CF Transport III Command Field Dual Voltage - Scaler, ultrasonic  
AEU-525CFH - TRANSPORT III WITH HANDPIECES MILITARY 110/220V DUAL VOLTAGE - Unit, operative dental  
AEU-525CFH - TRANSPORT III WITH HANDPIECES MILITARY 110/220V DUAL VOLTAGE - unit, operative dental  
AEU-525CFH-14 - TRANSPORT III WITH HANDPIECES and TIPS MILITARY 110/220V DUAL VOLTAGE - unit, operative dental  
AEU-525FO - TRANSPORT III W/FIBER OPTICS DUAL VOLT PORTABLE UNIT - unit, operative dental  
AEU-525S - TRANSPORT III W/SCALER DUAL VOLT UNIT 110/220V - Unit, operative dental  
AEU-525S - TRANSPORT III W/SCALER DUAL VOLT UNIT 110/220V - unit, operative dental  
AEU-6000 - IMPLANT SURGERY UNIT - Handpiece, direct drive, ac-powered  
AEU-6000 - IMPLANT SURGERY UNIT - Handpiece, direct drive, ac-powered  
AEU-6000-70V -IMPLANT SURGERY UNIT W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000-70V -IMPLANT SURGERY UNIT W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000ADN - IMPLANT SURGERY UNIT ADIN W/AE-70V FOOTSWITCH EURO CORD - Handpiece, direct drive, ac-powered  
AEU-6000ADN - IMPLANT SURGERY UNIT ADIN W/AE-70V FOOTSWITCH EURO CORD - Handpiece, direct drive, ac-powered  
AEU-6000ADN-110 - IMPLANT SURGERY UNIT ADIN W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000ADN-110 - IMPLANT SURGERY UNIT ADIN W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000ARM-70V -IMPLANT SURGERY UNIT ARGON MEDICAL W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000ARM-70V -IMPLANT SURGERY UNIT ARGON MEDICAL W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000GCR-70V - IMPLANT SURGERY UNIT GENICORE W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000GCR-70V - IMPLANT SURGERY UNIT GENICORE W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000GLI - IMPLANT SURGERY SYSTEM GLIDEWELL - Handpiece, direct drive, ac-powered  
AEU-6000GLI - IMPLANT SURGERY SYSTEM GLIDEWELL - Handpiece, direct drive, ac-powered  
AEU-6000GLI-70V - IMPLANT SURGERY SYSTEM GLIDEWELL W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000GLI-70V - IMPLANT SURGERY SYSTEM GLIDEWELL W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered  
AEU-6000-IVS-70V - IMPLANT SURGERY UNIT IMPLANT VISION W/AE-70V FOOTSWITCH - Handpiece,





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direct drive, ac-powered

AEU-6000-IVS-70V - IMPLANT SURGERY UNIT IMPLANT VISION W/AE-70V FOOTSWITCH - Handpiece,

direct drive, ac-powered

AEU-6000MG - IMPLANT SURGERY UNIT MEGAGENIMPLANT - Handpiece, direct drive, ac-powered

AEU-6000MG - IMPLANT SURGERY UNIT MEGAGENIMPLANT - Handpiece, direct drive, ac-powered

AEU-6000MIS-70V - IMPLANT SURGERY UNIT MIS W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000MIS-70V - IMPLANT SURGERY UNIT MIS W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000-OCO - IMPLANT SURGERY UNIT OCO BIOMEDICAL - Handpiece, direct drive, ac-powered

AEU-6000-OCO - IMPLANT SURGERY UNIT OCO BIOMEDICAL - Handpiece, direct drive, ac-powered

AEU-6000-OCO-70V - IMPLANT SURGERY UNIT OCO BIOMEDICAL W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000-OCO-70V - IMPLANT SURGERY UNIT OCO BIOMEDICAL W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000PDR-70V - IMPLANT SURGERY UNIT PDR W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000PDR-70V - IMPLANT SURGERY UNIT PDR W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000PTP-70V - IMPLANT SURGERY UNIT PALTOP W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000PTP-70V - IMPLANT SURGERY UNIT PALTOP W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000SAU - IMPLANT SURGERY UNIT STERNGOLD - Handpiece, direct drive, ac-powered

AEU-6000SAU - IMPLANT SURGERY UNIT STERNGOLD - Handpiece, direct drive, ac-powered

AEU-6000SAU-70V - IMPLANT SURGERY UNIT STERNGOLD W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000SAU-70V - IMPLANT SURGERY UNIT STERNGOLD W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000SDI-70V - IMPLANT SURGERY UNIT SPIRALTECH W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000SDI-70V - IMPLANT SURGERY UNIT SPIRALTECH W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-6000SWM - IMPLANT SURGERY SYSTEM SWEDEN & MARTINA - Handpiece, direct drive, ac-powered

AEU-6000SWM - IMPLANT SURGERY SYSTEM SWEDEN & MARTINA - Handpiece, direct drive, ac-powered

AEU-6000SWM-110 - IMPLANT SURGERY SYSTEM SWEDEN & MARTINA (US) - Handpiece, direct drive, ac-powered

AEU-6000SWM-110 - IMPLANT SURGERY SYSTEM SWEDEN & MARTINA (US) - Handpiece, direct drive, ac-powered

AEU-7000E - IMPLANT SURGERY SYSTEM ENDO - Handpiece, direct drive, ac-powered

AEU-7000E-70V - IMPLANT SURGERY SYSTEM ENDO W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-7000E-MG - IMPLANT SURGERY SYSTEM ENDO MEGAGEN - Handpiece, direct drive, ac-powered

AEU-7000E-MIS-70V - IMPLANT SURGERY SYSTEM ENDO MIS W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-7000E-SFI-70V - IMPLANT SURGERY SYSTEM ENDO SHATKIN W/AE-70V FOOTSWITCH - Handpiece, direct drive, ac-powered

AEU-7000L - IMPLANT SURGERY SYSTEM ENDO W/LIGHT - Handpiece, direct drive, ac-powered

AEU-7000L/7000L-70V IMPLANT SURGERY SYSTEM ENDO W/LIGHT - Handpiece, direct drive, ac-powered

AEU-7000L-70V - IMPLANT SURGERY SYSTEM ENDO W/AE-70V AND LIGHT - Handpiece, direct drive, ac-powered

AEU-7000L-MIS-70V - IMPLANT SURGERY SYSTEM ENDO MIS W/AE-70V AND LIGHT - Handpiece, direct drive, ac-powered

AEU-7000LNE-70V - IMPLANT SURGERY SYSTEM ENDO W/AE-70V2-10 NEOCIS - Handpiece, direct drive, ac-powered

AEU-7000LS - IMPLANT SURGERY SYSTEM ENDO SWEDEN & MARTINA W/AE-70V AND LIGHT - Handpiece, direct drive, ac-powered

AEU-707 FAMILY - Handpiece, direct drive, ac-powered





**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

**Certificate No. 9555-6-2025-1**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 6 of 6**

AEU-925 - Handpiece, direct drive, ac-powered  
AHP-03 - HPCE IRR/CABLE CLIP PKG OF 10 HOLDS IRRIG TUBE TO HMTR CABLE - Handpiece, direct drive, ac-powered  
AHP-04 - CANNULA W/NIPPLE & TUBING - Handpiece, direct drive, ac-powered  
AHP-05 - HPCE IRR/CONTRA ANGLE CLIP - Handpiece, direct drive, ac-powered  
AHP-06 - HPCE BODY CLIP - Handpiece, direct drive, ac-powered  
AHP-06 - HPCE BODY CLIP - Handpiece, direct drive, ac-powered  
AHP-07 - CANNULA CLIP SET - Handpiece, direct drive, ac-powered  
AHP-07 - CANNULA CLIP SET - Handpiece, direct drive, ac-powered  
AHP-07T - TUBE EXTERNAL IRRIGATION 6.5" L .042ID X .120OD - Handpiece, direct drive, ac-powered  
AHP-07T - TUBE EXTERNAL IRRIGATION 6.5" L .042ID X .120OD - Handpiece, direct drive, ac-powered  
ALU-40LED - LIGHT PORTABLE LED OPERATORY - LIGHT, OPERATING, DENTAL  
ALU-40LED-CF - LIGHT PORTABLE LED OPERATORY 6520-01-600-8241 - LIGHT, OPERATING, DENTAL  
ALU-40MOM - LIGHT PORTABLE LED OPERATORY MOM - LIGHT, OPERATING, DENTAL  
ALU-40MOM - LIGHT PORTABLE LED OPERATORY W/STAND MOM - LIGHT, OPERATING, DENTAL  
AMA-09A - KIT CUSPID CHAIN / GRID - WIRE, ORTHODONTIC  
AMA-09A2 - KIT BICUSPID CHAIN / GRID - WIRE, ORTHODONTIC  
AMA-09A3 - KIT INCISOR CHAIN / GRID - WIRE, ORTHODONTIC  
AMA-09D - LINGUAL BUTTONS PKG/6 - WIRE, ORTHODONTIC  
AMC-15 Basic Mobile Dental Cart - Unit, operative dental  
AMC-20 FAMILY - Unit, operative dental  
AMC-25 - MOBILE DENTAL CART AMC-25 - Unit, operative dental  
AMC-25 FAMILY - Unit, operative dental  
AMC-25CF - MOBILE DENTAL CART AMC-25CF - Unit, operative dental  
AMC-25CF-USAF - MOBILE DENTAL CART AMC-25CF-USAF - Unit, operative dental  
ASC-10-ACC - ACCESSORY KIT ASC-10 SCALER - Unit, operative dental  
ASC-10L-ACC - ACCESSORY KIT W/SLEEVE FOR LED ASC-10 SCALER - Unit, operative dental  
ASU-12-110 - AUTOCLAVE PORTABLE PRESTIGE CLASSIC 110V - Unit, operative dental  
ASU-12-230 - AUTOCLAVE PORTABLE PRESTIGE CLASSIC 230V - Unit, operative dental  
ATC-03CF - COMMAND AIR PORTABLE TRAY 6520-01-446-6263 - Unit, operative dental  
ATC-12V2 - CART 4 SHELF ADJUSTABLE WITH AC POWER - Unit, operative dental  
FUE-100 - MOTOR, SURGICAL INSTRUMENT, AC-POWERED  
I-14 - FORCEP RUBBER DAM - FORCEPS, RUBBER DAM CLAMP  
I-15 - TEMPLATE RUBBER DAM - FORCEPS, RUBBER DAM CLAMP  
I-16 - RUBBER DAM FRAME ADULT - FRAME, RUBBER DAM  
I-17 - RUBBER DAM FRAME CHILD - FRAME, RUBBER DAM  
I-18 - PUNCH RUBBER DAM - FORCEPS, RUBBER DAM CLAMP  
I-19 - RUBBER DAM PUNCH (IVORY STYLE) - FORCEPS, RUBBER DAM CLAMP  
I-70BM - HANDIDAM W/PLASTIC FRAME BLUE PKG OF 20 - DAM, RUBBER  
I-70BM-100 - HANDIDAM ASEPTICO MED BLUE-100 PKG OF 100 - DAM, RUBBER  
I-70K - CLAMP KIT HANDIDAM - DAM, RUBBER  
I-70LF - HANDIDAM-LF LATEX FREE RUBBER DAM MAUVE PKG OF 20 - DAM, RUBBER  
I-70LF-100 - HANDIDAM-LF LATEX FREE RUBBER DAM MAUVE PKG OF 100 - DAM, RUBBER  
NWS-7I - WATER SYS SELF-CONT INSTALLED NON-STERILE - Unit, operative dental  
NWS-8 - WATER SYSTEM - Unit, operative dental  
TA-1 - SYRINGE TIP AUTOCLAVABLE 3-WAY - Unit, operative dental  
TA-90VC - SYRINGE TA-90 VALVE CARTRIDGE - Unit, operative dental  
-----END OF PRODUCT LIST-----

