



Certificate No. 2037-11-2017

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

(Five 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.

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 November 20, 2017 to November 19, 2019.





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 Owner Operator

HENRY SCHEIN, INC.
135 DURYEY RD.
Melville, NY USA 11747

HENRY SCHEIN, INC. C/O UPS SCS
RD1 KM 25.3 BO Quebrada Arenas
Caguas, PR USA 00725

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

Name of Distributor

HENRY SCHEIN INC. (DENTAL DIVISION)
16515 W Beloit Rd
New Berlin, WI USA 53151

HENRY SCHEIN, INC.
41 WEAVER RD.
DENVER, PA USA 17517

HENRY SCHEIN, INC.
1001 NOLEN DRIVE, BLDG 3
SUITE 400
GRAPEVINE, TX USA 76051

HENRY SCHEIN, INC.
5315 WEST 74TH ST.
INDIANAPOLIS, IN USA 46268

HENRY SCHEIN, INC.
8691 JESSIE B. SMITH COURT
JACKSONVILLE, FL USA 32219

HENRY SCHEIN, INC.
255 VISTA BLVD.
SPARKS, NV USA 89434





U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR DEVICE & RADIATION HEALTH

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Name of Product(s)

Bouffant Cap White Poly 21" 100/Bx 0
Cover Shoe Unisex Blue 50Pr/Bx One Size
Adapted Face Mask 50/Bx Blue
Self Seal Sterilization Pouch 200/Bx 2.75x9
Self Seal Sterilization Pouch 200/Bx 3.5x5.25
Self Seal Sterilization Pouch 200/Bx 5.25x12
Disp Cover Gown Blue Fluid Res 10/Pk Med/Large
Economy Molded Face Mask 50/Bx Blue
Cotton Rolls #2 Non Sterile 2000/Bx 1.5"
Earloop Mask 50/Bx Yellow
Earloop Mask 50/Bx Blue
HSI Bouffant Cap Poly Blue 100/Bx 21"
Self Seal Sterilization Pouch 200/Bx 3.5x9
Self Seal Sterilization Pouch 200/Bx 5.25x10
Self Seal Sterilization Pouch 200/Bx 2.25x4
Amalgam Carrier DE Steel Ea Medium-Large
Saliva Ejector Clear 100/Pk w/Blue Tip
Ultrasound Gel Clear Ea 5 Liter
FX-54 Vinyl Packet Size 0 100/Bx 1 Film
FX-58 Vinyl Packet Size 2 150/Bx 1 Film
Evacuator Tips Vented 50/Bg Disposable
Earloop Mask Procedural 50/Bx Pink





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Maxima Multi Parameter Pouch 200/Bx 3.5x9
Maxima Multi Parameter Pouch 200/Bx 5.25x10
Maxima Multi Parameter Pouch 200/Bx 2.25" x 4"
VP Mix Putty Reg Set Kit 2/Pk 300mL
Blu-Bite HP Regular Set 2/Bx 0
VP Mix HP Regular Set 4/Bx Monophase
VP Mix HP Regular Set 4/Bx Light Body
Autoclavable Syringe Tips 6/Pk 0
Acclean Pro Ultrasonic Scaler Ea 25KHZ
Schein Alginate Regular Set 1Lb 0
Schein Alginate Fast Set 1Lb 0
Sure Tip 250/Pk Clear
All-Gauze Sponge Non Sterile 200/Bg 2"x2" 12ply
All-Gauze Sponge Non Sterile 200/Pk 2"x2" 8ply
Exodontia Sponge Filled N/S 5000/Ca 2"x2"
Premium Non-Woven Sponge NS 200/Pk 2"x2" 4ply
Acclean Prophy Paste Fine 200/Bx Bubblegum
Acclean Prophy Paste Coarse 200/Bx Bubblegum
Acclean Prophy Powder 13oz/Bt 0
Ionosphere Caps Reg Set 500/Jr 1 Spill
C-Type Handpiece Ea 4 Hole
C-Type Mini Handpiece Ea 4-Hole
C-Type Mini Push-Button Handpc Ea 4-Hole
CU-1000 Halogen Curing Light Ea w/Lightmeter
C-Type Push Push-Button Handpc Ea 4-Hole
Spray & Clean 6oz Can Ea 6oz
Compo-Post Long Assorted 12/Bx 0
Compo-Post Medium Assorted 12/Bx 0
Screw Post Gold Plated 12/Bx #2 Long
Screw Post Gold Plated 12/Bx #1 Long
Compo-Post Long 12/Bx #3
Screw Post Gold Plated 12/Bx #3 Long
Compo-Post Long 12/Bx #2
Compo-Post Long 12/Bx #1
Gapped Strips Dual Purpose 150/Bx 0
Silicone Endo Stops 100/Bx Assorted
Contra Angle 20,000 RPM Ea #150
Mirror Simple Stem FS #5 12/Bx 0
Mouth Gag Molt Child Ea 0
Forcep Extracting Ea #222
Bone File DE 12 Howard Ea 0
Mirror Handle Deluxe Octagonal Ea Simple Stem
Excavator DE Ea #17
Forcep Extracting Ea #18R
Plastic Filling Instrument DE Ea PF
Curette Gracey DE 11/12 Ea Hollow
Scaler Younger SE 15 Ea 0
Curette Gracey DE 13/14 Ea Hollow
Excavator DE Ea #18
Forcep Extracting Ea #23
Curette Gracey DE 3/4 Ea Hollow
Needle Holder Mayo-Hegar 6" Ea Standard
Plastic Filling Instrument DE Ea PF4
Scissor Iris 4.5" Straight Ea Standard
Curette Gracey DE 5/6 Ea Hollow
Mirror Simple Stem FS #3 12/Bx 0
Carver DE Hollenback Ea #3
Spreader SE #D11T Ea 0





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Cotton Plier 317 College Ea Serated Tips
Forcep Extracting Ea #18L
Forcep Extracting Ea #32
Probe Williams SE Round Ea 0
Curette Bone DE Lucas Ea 85
Hemostat Halsted Mosquito 5" Ea Str Standard
Hemostat Halsted Mosquito 5" Ea Curv Standrd
Elevator Apical #302 Ea 0
Curette Gracey DE 7/8 Ea Hollow
Adson Dressing Forcep Economy Ea 4-3/4"
Forcep Extracting Ea #150
Tissue Adson Forcep Econo 1x2 Ea 4-3/4"
Curette McCalls DE 17/18 Ea Hollow
Scissor Littauer Jr 4.5" Ea Standard
Curette McCalls DE 13/14 Ea Hollow
Forcep Extracting Ea #65
Mirror Handle Deluxe Round Ea Simple Stem
Elevator Apical #303 Ea 0
Curette Gracey DE 1/2 Ea Hollow
Discoïd & Cleoid DE 89/92 Ea Carver
Excavator DE Ea #19
Surgical Handle Ea #3
Forcep Extracting Ea #151
Elevator Apical #301 Ea 0
Explorer DE #5 Ea 0
Black DE Cavity Prep Ea 51/52
Forcep Extracting Ea #16
Scissor Iris 4.5" Curved Ea Standard
Explorer DE DG16 Ea 0
Tofflemire Matrix Retainer Ea Universal
Aspirating Syringe C-W Type Ea 1.8cc
Excavator DE #31L Ea Solid Handle
Plugger Amalgam Hollenback #2 Ea DE
Excavator DE #33L Ea Solid Handle
Plugger Amalgam Hollenback #1 Ea DE
Margin Trimmer DE 26 Ea 0
Curette Gracey DE 17/18 Ea Hollow
Expro Probe Explorer 23/CP12 Ea 0
Curette Gracey DE 9/10 Ea Hollow
Margin Trimmer DE 28 Ea 0
Burnisher DE 27/29 Ea 0
Scaler Jacquette DE 31/32 Ea Hollow Handl
Scaler Jacquette DE 30/33 Ea Hollow Handl
Plugger Amalgam Hollenback #3 Ea DE
Burnisher DE 21 Ea 0
Margin Trimmer DE 27 Ea 0
Curette Gracey DE 15/16 Ea Hollow Handl
MaxiGrip McCalls DE 13/14 Ea SS
MaxiGrip Gracey DE 17/18 Ea SS
Rubber Dam Frame Ea 5x5
Rubber Dam Frame Ea 6x6
Cord Packing Instrument Circle Ea Serrated
Cord Packing Instrument Std Ea Serrated
Interdental Wedges Small 400/Bg Pink
Amalgam Gun Ea Curved
General Purpose Cleaner 24/Bx Unit-Dose
Gates Glidden Drills RA 32mm 6/VI #3
Gates Glidden Drills RA 32mm 6/VI #6





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Peeso Reamers RA 19mm 6/Pk #2
Gates Glidden Drills RA 32mm 6/VI #4
Luks Finger Plugger 25mm A-D 4/Pk Assorted
Engine Reamers 25mm 6/Pk #15-40
Paste Fillers RA 25mm 4/Bx #1-4
Carbide Bur FG 4 10/Pk 0
Gates Glidden Drills RA 32mm 6/VI #1
Peeso Reamers RA 19mm 6/Pk #3
Peeso Reamers RA 19mm 6/Pk #6
Carbide Bur HP 8 10/Pk 0
Gates Glidden Drills RA 32mm 6/VI #2
Gates Glidden Drills RA 32mm 6/VI #5
Peeso Reamers RA 19mm 6/Pk #1
Peeso Reamers RA 19mm 6/Pk #5
Peeso Reamers RA 19mm 6/Pk #4
Carbide Bur Surgical FG 151 5/Pk 23mm
Suture Silk Black C-6 12/Bx 4-0 18"
Suture Silk Black C-6 12/Bx 3-0 18"
Suture Chromic Gut Undyed C-6 12/Bx 3-0 27"
Suture Chromic Gut Undyed C-6 12/Bx 4-0 27"
Acclean Fluoride Varnish 50/Bx Bubblegum
Essentials Towels 2Ply+Poly 500/Ca Lavender
Essentials Towels 2Ply+Poly 500/Ca Green
Essentials Towels 2Ply+Poly 500/Ca Aqua
Essentials Towels 2Ply+Poly 500/Ca Blue
Gutta Percha Points Cadm Free 100/Bx #20
Gutta Percha Points Cadm Free 100/Bx #40
Gutta Percha Points Cadm Free 100/Bx #35
Gutta Percha Pts CadmiumFree 100/Bx Medium-Fine
Gutta Percha Pts CadmiumFree 100/Bx Fine
Gutta Percha Points Cadm Free 150/Bx #15-40
Gutta Percha Points Cadm Free 100/Bx #25
Gutta Percha Points Cadm Free 150/Bx #45-80
Gutta Percha Points Cadm Free 100/Bx #30
Gutta Percha Points Cadm Free 100/Bx #15
Maxima Gutta Percha CC 20/VI 6VIs/Bx #15-40
Maxima Gutta Percha CC 20/VI 6VIs/Bx #45-80
Absorbent Pts Cell Pk#506 180/Bx #15-40
Maxima Absorb Pts CC#501 200/Bx #15
Maxima Absorb Pts CC#501 200/Bx #20
Maxima Absorb Pts CC#501 200/Bx #25
Maxima Absorb Pts CC#501 200/Bx #30
Maxima Absorb Pts CC#501 200/Bx #35
Maxima Absorb Pts CC#501 200/Bx #40
Maxima Absorb Pts CC#501 200/Bx #45
Maxima Absorb Pts CC#501 200/Bx #15-40
Maxima Absorb Pts CC#501 200/Bx #45-80
Tubes and Plugs Low Viscosity 100/Pk Amber
Micro Applicators Fine 100/Pk Pink
Dri-Gard Cotton Roll Subs 50/Bx Large
Arch Wire SS Round 14" Long 10/PK .016
Cheek Retractor Universal Ea 0
Cheek Retractor DE 5-3/4 2/PK Small
Irrigating Needles Side Vent 100/Bg 27Ga
Zircon F Prophy Paste 10oz/Jr Bubblegum
Aspirator Tip Surgical Blue 25/Pk 1/16" dia
Mouth Props Black LF Rubber 2/Bx Child
Mylar Matrix Strips .002 1000/Bx 0





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GOVERNMENT OF NEW HAMPSHIRE DEPARTMENT OF HEALTH

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Articulating Paper Combination 12Bks/BxRed/Blue

Surgeon Blades SS Sterile 100/Bx #15

Tissue Conditioner Ea Complete Pk

Barbed Broaches NS Red 3 10/Pk XF

Barbed Broaches NS White - 1 10/Pk XXXF

Barbed Broaches NS Green 5 10/Pk Med

Barbed Broaches NS Blue 4 10/Pk Fine

Barbed Broaches NS Yellow 2 10/Pk XXF

Barbed Broaches NS Purple O 10/Pk XXXXF

Barbed Broaches NS Black 6 10/Pk Coarse

Dental Dam 6x6 Green 36/Bx Medium

Criterion PC Glove PF Latex 100/Bx Small

Criterion PC Glove PF Latex 100/Bx Medium

Criterion PC Glove PF Latex 100/Bx Large

Criterion Glove PF Nitrile LF 100/Bx Small

Criterion Glove PF Nitrile LF 100/Bx Medium

Criterion Glove PF Nitrile LF 100/Bx Large

Caries Indicator Syringe Kit 4/Bx Red

Composite Paste-Paste 28gm/Ea Kit

Softline Chairside Reline Kit Ea Material Pk

Etch Gel Syringe Kit 40% 4/Bx 1.2mL

Chairside Reline Material Ea Pack

Multi-Use Dispenser Ea 0

Natural Elegance Pit & Fissure 4/Pk Sealant Kit

Standard Needles 27Ga Long 100/Bx Plastic Hub

Standard Needles 27Ga Short 100/Bx Plastic Hub

Standard Needles 30Ga Short 100/Bx Plastic Hub

Standard Needles 30Ga X-Short 100/Bx Plastic Hub

Sterilization Tubing Cont Clr 100/RI 2x100

Sterilization Tubing Cont Clr 100/RI 3x100

Steam Autoclave Indicator Tape RI 3/4"

Steam Autoclave Indicator Tape RI 1"

Eugenol Ea 4oz/Bt

Acclean Disp Prophy Angle 100/Bx Firm Wht

Acclean Disp Prophy Angle LF 100/Bx Firm Cup-GR

Rongeur Mead 1A Ea German SS

Rongeur Blumenthal 6 Ea German SS

Prophy Cups Ribbed Latch Type 36/Bx Soft Gray

Prophy Cups Webbed Latch Type 36/Bx Hard White

Disposable Prophy Angle 100/Bx Firm White

Disposable Prophy Angle LF 100/Bx Long Soft

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

