



EC Declaration of Conformity

Manufacturers Name: Zirc Dental Products, Inc.

Manufacturers Address: 3918 Highway 55 Southeast
Buffalo, Minnesota 55313
USA

Authorized Representative Name: Loser & Co. GmbH

Authorized Representative Address: Benzstrasse 1c
51381 Leverkusen
Germany
Europe

Issued Basic UDI-DI and REF Numbers: See Attachment to Declaration of Conformity

Issued Basic UDI-DI(s) and Name of Device Groups:

- 0840161300012Z: Non-Sterile Dental E-Z Access Shelving, Handi-Hopper & Accessories, Waste Drop Ring
- 08401613000233: Non-Sterile Dental Natural Latex, Latex-Free Insti-Dam Relaxed Fit & Latex-Free Insti-Dam
- 08401613000335: Non-Sterile Dental Organizational Trays, Tubs & Covers, Instrument Mat, Cotton Roll Dispenser, Pellet Dispenser, Insta-Dam Dispenser, Restorative Organizer, Implant Organizer, Bur Block Covers, Capsule & Syringe Composite Kits, Shade Label Sheets, Tub Cups & Covers, Tub Dividers, Liners & Inserts, Syringe and Capsule Clip-On Holders, Syringe 20-Unit Stand & Syringe 10-Unit Stand Add-On
- 08401613000437: Non-Sterile Denture & Retainer Boxes
- 08401613000539: Non-Sterile Dental Steri-Containers, Instrument Cassettes, Compact Cassette, Instrument Mats, Steri-Bur & Endo Guards, Bur Blocks, Syringe Tip Holder, E-Z ID Rings & Tape
- 0840161300063B: Non-Sterile E-Z Storage Rack & Multi-Mod Racks for Organizational Purposes
- 0840161300073D: Non-Sterile Steri-Endo Foam Inserts & Endo Assist Stand Foam
- 0840161300083F: Non-Sterile Dental Organizing E-Z ID Rings
- 0840161300093H: Non-Sterile Matrix Dispenser
- 084016130001032: Non-Sterile Dental Dispos-A-Screen Trap, Saliva Ejector Screen & Cuspidor Screen
- 084016130001134: Non-Sterile Dental Steri-Soaker
- 084016130001236: Non-Sterile Dental Needle Capper



084016130001338: Non-Sterile Dental Mouth Mirrors, Mirror Handles & Mirror Heads

08401613000143A: Non-Sterile Dental Water Wise Kit & Replacement Bottle

08401613000173G: Non-Sterile Mixing Sticks, Bowls & Wells

08401613000183J: Non-Sterile Mighty Mixer Spatula, Cement Spatula & Delrin Spatula

08401613000193L: Non-Sterile Saliva Ejector Valve, Replacement Tip & Valve Lever

0840161300020NC: Mirror Magic® Anti-Fog Solution, Swipe Pads & Organizer, Mirror Magic® Trial Kit, Clarity Collection

0840161300021NE: Non-Sterile Airway Armor Aspiration Prevention & Pink Petal Hands-Free Isolation

Product Identification: See Attachment to Declaration of Conformity

Risk Classification: Class I: EC declaration of Conformity according to annex VIII

Conformity Assessment Route: The devices have been designed and manufactured in compliance with the GENERAL SAFETY AND PERFORMANCE REQUIREMENTS according to the Regulation (EU) 2017/745 specified in Annex I, in combination with the applicable requirements of Annex II and Annex III. Furthermore, we declare and assure, that the devices covered by this declaration comply with other relevant Union legislation providing for the issuance of an EU declaration of conformity, if applicable.

This declaration of conformity is issued under the sole responsibility of Zirc Dental Products, Inc. This declaration is supported by the Quality System approval to ISO 13485 issued by Intertek Medical Notified Body AB. All supporting documentation is retained at the premises of the manufacturer.

Signature:

Date (dd.mmm.yyyy) of issue:

Kim Vest PRRC
Name & Function

27 May 2021



Attachment to Declaration of Conformity

Basic UDI-DI	Reference Number / Product Name
0840161300012Z	20Z420 / E-Z Access Shelf 20Z422 / E-Z Access Shelf Adapters 20Z424 / E-Z Access Shelf Surface Mount 20Z426 / E-Z Access Shelf Wall or Cabinet Mount 20Z428 / E-Z Access Shelf 8" Extension Arm 20Z436 / E-Z Access Shelf Cup Holder-Snap On 20Z437 / E-Z Access Shelf 3-1/2in. Bolt Adapter Kit 20Z438 / E-Z Access Shelf 4-1/2in. Bolt Adapter Kit 20Z404 / Handi-Hopper 20Z405 / Handi-Hopper Liners Red Biohazard 20Z408 / Handi-Hoppers Bracket 20Z410 / Handi-Hopper Liners Clear 22Z100 / Waste Drop Ring
0840161300023Z	50Z455 / Natural Latex Insti-Dam 50Z457 / Latex-Free Insti-Dam Relaxed Fit 50Z459 / Blue Latex-Free Insti-Dam
0840161300033Z	20Z401 / B-Lok Flat Tray 20Z451 / B-Lok Divided Tray 20Z101 / Mini Tray 20Z445 / B-Size Safe-Lok® Tray Cover 20Z446 / B-Size Safe-Lok® Cover Tall 20Z441 / B-Size Tray Cover Non-Locking 20Z103 / Mini-Lok Tray Cover 20Z102 / Mini Tray Cover Non-Locking 20Z463 / Procedure Tub 20Z464 / Instrument Mat 29R605 / E-Z Storage Tub (w/white cover) 29R610 / E-Z Storage Tub (w/clear cover) 20Z201 / No. 16A Hand Instruments (Regular Well) Cabinet Tray 20Z202 / No. 16 Hand Instruments (Deep Well) Cabinet Tray 20Z203 / No. 17 Clamps, Retainers, etc. Cabinet Tray 20Z204 / No. 18 Finishing Strips Cabinet Tray 20Z205 / No. 19 Pliers, Scissors, etc. Cabinet Tray 20Z206 / No. 20 Discs, Wheels, Stones Cabinet Tray 28R800 / Deluxe Cotton Roll Dispenser 28R825 / Pellet Dispenser for Small Pellets 28R850 / Pellet Dispenser for Medium Pellets 50Z471 / Insti Dam Dispenser 20Z495R / Restorative Organizer 20Z490B / Implant Organizer

Basic UDI-DI	Reference Number / Product Name
	50Z401 / 8-hole Bur Block Cover 1in. High-Standard 50Z404 / 14-hole Bur Block Cover 1in. High-Standard 50Z405 / 14-hole Bur Block Cover 2in. -HP Lab Burs 20Z479 / Capsule Composite Kit 20Z489 / Syringe Composite Kit 20Z455 / Complete Tub 20Z463 / Shade Label Sheets 20Z459 / Safe-Lok® Tub Cover 20Z471 / Single Tub Cup with Cover 20Z472 / Double Tub Cup with Cover 20Z473 / Long Tub Cup with Cover 20Z461 / Tub Dividers 20Z462 / Tub Liner 20Z466 / Divided Slide Tray 20Z467 / Flat Slide Tray 20Z465 / Tub Insert 20Z486 / Syringe Clip-On Holder 20Z476 / Capsule Clip-On Holder 20Z487 / Syringe 20-Unit Stand 20Z488 / Syringe 10-Unit Stand Add-On
08401613000437	30X800 / Denture Box 25X500 / 1in. Deep Retainer Box 25X550 / 1.5in. Deep Retainer Box
08401613000539	20Z480 / Mini Mat 20Z464 / Instrument Mat 50Z917 / Compact Cassette and Mini Matt Strap 50Z919 / Compact Cassette and Mini Matt Feet 50Z406 / Steri-Bur Guard 12-Hole 50Z408 / Steri-Bur Guard Tall 12-Hole 50Z410 / Steri-Bur Guard 22-Hole 50Z412 / Universal Short Bur Adapter Tall 50Z400 / Bur Block Magnetic 8-Hole 50Z403 / Bur Block Magnetic 14-Hole 50Z450 / Steri-Endo Guard Hand 50Z452 / Steri-Endo Guard Engine 50Z460 / Endo Assist 50Z462 / Assist Stand 50Z915 / Compact Cassette 50Z925 / E-Z Jett® Cassette 5-place 50Z927 / E-Z Jett® Cassette 8-place 50Z911 / E-Z Jett® Slim 8-place 50Z930 / E-Z Jett® Cassette 10-place

Basic UDI-DI	Reference Number / Product Name
	50Z940 / Performance Tool Organizer 50Z900 / Steri-Container 50Z905 / Compact Steri-Container 50R925 / E-Z Jett® Feet 50Z926 / Syringe Tip Holder
0840161300063B	29R650 / E-Z Storage Single Rack 21Z410 / Multi-Mod Rack (8-Place) 21Z105 / Multi-Mod Rack (6-Place)
0840161300073D	50Z451 / Steri-Endo Foam Inserts 50Z466 / Endo Assist Stand Foam
0840161300083F	70Z100 / E-Z ID Rings Small 70Z200 / E-Z ID Rings Large 70Z000 / E-Z ID Rings X-Large 70Z115 / E-Z ID Rings Jewel System Small 70Z215 / E-Z ID Rings Jewel System Large 70Z015 / E-Z ID Rings Jewel System X-Large 70Z110 / E-Z ID Rings Vibrant System Small 70Z210 / E-Z ID Rings Vibrant System Large 70Z010 / E-Z ID Rings Vibrant System X-Large 70Z105 / E-Z ID Rings Classic System Small 70Z205 / E-Z ID Rings Classic System Large 70Z005 / E-Z ID Rings Classic System X-Large 70Z300 / E-Z ID Tape Roll 70Z315 / E-Z ID Tape System - Jewel 70Z310 / E-Z ID Tape System - Vibrant 70Z305 / E-Z ID Tape System - Classic
0840161300093H	55Z200 / Matrix Dispenser
084016130001032	51Z045 / Dispos-A-Screen Trap 2 1/8in. 51Z123 / Dispos-A-Screen Trap 1 7/8in. 51Z070 / Dispos-A-Screen Trap 2 3/4in. 51Z040 / Dispos-A-Screen Trap 2 1/4in. 51Z060 / Dispos-A-Screen Trap 2 7/8in. 51Z080 / Dispos-A-Screen Trap 1 1/4in. 51Z050 / Dispos-A-Screen Trap 2 5/8in. 50Z952 / Saliva Ejector Screen 51Z200 / Cuspidor Screen Small 51Z205 / Cuspidors Screen Large
084016130001134	50Z805 / Steri-Soaker
084016130001236	27R700 / Needle Capper Standard 27R704 / Needle Capper Long
084016130001338	50Z302 / Illuminator Mouth Mirror 50Z347 / Ergo Grip Handle (Simple Stem)

Basic UDI-DI	Reference Number / Product Name
	50Z342 / Ergo Grip in Cone Socket 50Z340 / Soft Grip in Cone Socket 50Z353 / Crystal HD Mouth Mirror #4 Thin Grip 50Z354 / Crystal HD Mouth Mirror #5 Thin Grip 50Z361 / Crystal HD Mouth Mirror Black/Gray Soft Grip 50Z362 / Crystal HD Mouth Mirror Black/Gray Soft Grip 50Z363 / Crystal HD Mouth Mirror #4 Soft Grip 50Z364 / Crystal HD Mouth Mirror #5 Soft Grip 50Z371 / Crystal HD Plastic Head #4 50Z372 / Crystal HD Plastic Head #5 50Z374 / Crystal HD Double-Sided Mirror Head #4 50R378 / Stainless Steel Mirror #0 50R379 / Stainless Steel Mirror #3 50R380 / Stainless Steel Mirror #4 50R381 / Stainless Steel Mirror #5 50R388 / Stainless Steel Head #0 50R389 / Stainless Steel Head #3 50R390 / Stainless Steel Head #4 50R391 / Stainless Steel Head #5 50Z392 / Plastic Screw-on Heads #4 50Z393 / Plastic Screw-on Heads #5 50Z394 / Double-Sided Mirror Head
08401613000143A	23Z100 / Water Wise Starter Kit 23Z105 / Water Wise Replacement Bottle
08401613000173G	50Z521 / Mixing Sticks 50Z505 / Mighty Mixer Bowls 20Z496 / Mixing Well
08401613000183J	50Z501 / Mighty Mixer Spatula 50Z502 / Cement Spatula 50Z523 / Delrin Spatula
08401613000193L	23E365 / Saliva Ejector Valve 23E363 / Saliva Ejector Replacement Tip 23E364 / Saliva Ejector Valve Lever
0840161300020NC	50R205 / Mirror Magic® Anti-Fog Solution 50R210 / Swipe Pads 50R201 / Organizer 50R200X / Mirror Magic® Trial Kit 50R220 / Clarity Collection
0840161300021NE	50Z960 / Airway Armor 50Z975 / Pink Petal