



EU- Declaration of Conformity

issued under the sole responsibility of the manufacturer listed below:

Manufacturer's Name	HU-FRIEDY MFG. CO., LLC
Manufacturer's address/ SRN	3232 N. Rockwell St. Chicago, IL 60618 USA SRN: US-MF-000017104
EU Representative Address/ SRN	Hu-Friedy Europe LLC & Co. KG Kleines Öschle 8 78532 Tuttlingen Germany SRN: DE-AR-000005530
Quality System Cert No.	MP19.8418
Notified Body No./Name	N/A. Class I device

As the manufacturer listed above, we declare that the devices listed:

Product(s):	See attachment 1
REF:	See Attachment 1
Basic UDI-DI:	0889950Hinged17F
Intended Purpose:	Nonsurgical instruments to grasp, hold, or cut materials, having a hinge

meets all conformity requirements of the safety and performance requirements of the Medical Devices Regulation (MDR, Regulation (EU) 2017/745 as amended).

Product classification according to the requirements described in **Annex VIII** of the Medical Devices Regulation, the medical device is assigned to risk **class I**. (conformity assessment per **Annex IV and V**).

Applied standards: ISO 15223-1, ISO 13485, ISO 14971

Signature: Kimberly Ball

Title: Regulatory Affairs Specialist

Place of Issue: Chicago, IL USA

Date of Issue: June 28, 2023



Attachment 1: Part Code List

Part Number	Description
678-001	Replacement Blade for 678-206
678-002	Replacement Blade for 678-303
678-014	1/4" Replacement Pads - 678-207/208,6pk
678-014A	1/4" Replacement pads for 678-206 6pk
678-018	1/8" REPLACEMENT SET SCREW AND HEX KEY
678-020	Torquing Key .016" x .018"
678-021	Torquing Key .019" / .022"
678-036	3/16" Replacement Pads - 678-207/208,6pk
678-101	Universal Distal End Cutter w/hold
678-101L	Long Handle Universal Cutter w/hold
678-102	Universal Distal End Cutter
678-103	Hard Wire Cutter 15 Degrees
678-104	Hard Wire Cutter, Straight
678-105	Pin & Ligature Cutter
678-106	Mini Pin & Ligature Cutter
678-107	Micro Mini Pin & Ligature Cutter
678-107L	Long Handle Micro Mini Pin & Lig Cutter
678-109	15 Degree Micro Mini Ligature Cutter
678-110	Micro Cutter
678-111	DISTAL END CUTTER FLUSH CUT W/ HOLD
678-113	Slim Flush Cut & Hold Distal End Cutter
678-114	Slim Flush Cut&Hold Distal Cutter O-Ring
678-114R150	O-Ring Refills for 678-114, 150 pk
678-114R50	O-Ring Refills for 678-114, 50 pk
678-200	Ultra Slim Weingart Pliers
678-201	Weingart Pliers
678-201L	Long Handle Weingart Pliers
678-202	Slim Weingart Pliers
678-203	How Pliers, Straight
678-204	How Pliers, Offset
678-205	Band Seating Pliers
678-206	Adhesive Removing Pliers
678-207	Band Removing Pliers, Long
678-208	Band Removing Pliers, Short
678-210	Force Module Separating Pliers
678-211	Ligature Tying Pliers, Coon Style
678-212	Direct Bond Bracket Holder (tweezers)
678-212M	Direct Bond Bracket Holder (tweezers)
678-216	TIP BACK PLIERS
678-219	Bracket Removing Pliers, Straight
678-220L	Angulated Bracket Remover Pliers



678-221	Crown & Band Contouring Pliers
678-221M	Crown & Band Contouring Pliers Modified
678-221MC	Crown & Band Contouring Pliers, Modified
678-222	STEINER TYING PLIERS
678-225	Band Crimping Pliers Orthodontic
678-225M	Band Crimping Pliers, Modified
678-301	Jarabak Pliers
678-302	Three Jaw Pliers
678-303	Omega Loop Forming Pliers
678-304	Bird Beak Pliers
678-305	Light Wire Bird Beak Pliers w/Groove
678-306	Tweed Loop Forming Pliers
678-307	Arch Bending Pliers
678-307S	Tweed Pliers, Slim
678-308	Rectangular Arch Bending Pliers
678-309	Lingual Arch Forming Pliers
678-310	Hollow Chop Contouring Pliers
678-311	O'Brien Pliers
678-312	Mini Three Jaw Pliers
678-315	General Contouring Pliers
678-316	Marcotte Looping Pliers
678-317	Hollow Chop Pliers
678-318	Light Wire Bird Beak Pliers
678-319	Nance Pliers
678-320	Adams Pliers
678-321	V-Stop Pliers
678-322	Ni-Ti Pliers, 3-Prong
678-323	Optical Pliers
678-324	Old Style Loop Pliers
678-325	Bird Beak with Cutter
678-326	Long Tapered Bird Beak Pliers
678-327	Hammerhead Ni-Ti Bender Pliers
678-328-20	Torquing Pliers with Key .016" / .018"
678-328-21	Torquing Pliers With Key .019" / .022
678-330	Mathieu Pliers-Ortho
678-331	Mathieu Pliers, Ortho Wide Tip
678-332	Mathieu Pliers, Ortho Perma Sharp
678-340	Ortho Step Pliers, 1/2MM
678-341	Ortho Step Pliers, 3/4MM
678-342	Ortho Step Pliers, 1MM
678-500	Slim Line Micro Cutter
678-501	Slim Line Weingart Pliers
678-502	Slim Line Hammerhead NiTi Pliers
678-503	Slim Line Band Remover Pliers
678-504	Slim Direct Bond Bracket Holder Tweezers
678-505	Ultra Slim Buccal Tweezers
678-506	Slim Line Distal Cinch Back Hand Instr



678-700	Lingual Distal End Cutter
678-701	Lingual Pin & Lig Cutter
678-702	Lingual Weingart Pliers
678-702-90	Lingual Weingart Pliers - 90 degrees
678-703	Lingual Bracket Removing Pliers
678-704	Lingual Hammerhead NiTi Pliers
678-704SER	Lingual Hammerhead NiTi Pliers, Serrated
678-705	Lingual Mathieu Pliers
678-709	Lingual Debonding Pliers
678-800	The Tear Drop Cutter
678-801	The Vertical Pliers
678-802	The Horizontal Pliers
678-803	The Hole Punch Cutter, 6mm
678-804	The Spot
678-805	The Petite Punch
678-806	The Edge
678-807	The Mesial Wedge
678-808	The Distal Wedge
678-809	The Bite Plane
678-810	The Bootstrap Punch
678-811	The Eraser
MGA	Molt Mouth Gag, Adult Size
MGC	Molt Mouth Gag, Child Size
MGI	Molt Mouth Gag, Infant Size
RDF	Rubber Dam Forceps
RDF4	Rubber Dam Forceps #4
RDF4E	Rubber Dam Forceps #4
RDP	Rubber Dam Punch
RDPA	Rubber Dam Punch-Ainsworth
TC3	Backhaus Towel Clamp - 3 1/4in
TC5	Backhaus Towel Clamp - 5in
WBP137	#137 Gordon Pliers
WCS	Wire Cutting Scissors, Angled
WTD6C	Wire Twister Delicate 6in TC
WTD7C	Wire Twister Delicate 7in TC
SMS11/12XCE2	#11/12 Micro Gracey, EE2, Harmony, Ornge
SMS13/14XCE2	#13/14 Micro Gracey, EE2, Harmony, Blue
WCSS	Wire Cutting Scissors Smith 15cm