



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 covered under MDD

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

Product(s):	See attachment 1
REF:	See Attachment 1
Intended Purpose:	Instrument to grasp, hold, cut or remove oral tissues, having a hinge and being used ultimately next to or in an artificially created orifice

Are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; and

Product classification according to the requirements described in **Annex IX** of Directive 93/42/EEC, the medical device is assigned to risk **class I** (conformity assessment per **Annex VII**)

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

Signature: Jennifer A. Rieck

Title: Senior Regulatory Affairs Specialist

Place of Issue: Chicago, IL USA

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Attachment 1: Part Code List

Part Number	Description
150-001	Suture Scissors (Super Cut) curved 12 cm
150-002	Scissors Iris Gingiva 12 cm Curved
150-003	Micro Scissors Castroviejo 15 cm
150-004	Scissors LaGrange #14
150-005	Scissors Iris Straight #17 11.5cm
150-006	Scissors Surgical #22 14.5cm
151-001	Nadelhalter Mathieu gerade, 14cm
151-002	Crile-Wood Needle Holder
152-001	Friedman Rongeurs
155-002	Needle Holder Castroviejo 15cm Straight
157-001	Universal Paen Hemostat
160-001	Forcep European Style #1
160-004	Forceps #4 Europ. IM anterior
160-007	Forcep European Style #7
160-013	Forceps European Style #013
160-017	Forceps European Style #17
160-018	Forcep European Style #18
160-022	Forceps European Style #022
160-033	Forceps European Style #033
160-046L	Forceps European Style #046L
160-051	Forceps European Style #51
160-067A	Forceps European Style #067A
160-079	Forceps European Style #79
CBBC	Cortical Bone Block Clamp
F1	#1 Standard Forceps
F101	#101 Hull Forceps
F10S	#10S Forceps



F13XS	13 Atraumair Forceps, Lower Premolars
F150	#150 Cryer Forceps
F150A	#150A Cryer Forceps
F150AS	#150AS Split Beak Forceps, Serrated
F150IS	150 Upper Universal, IS Forceps
F150K	#150 Forceps Small Pedo
F150S	#150S Pedo Forceps
F150SR	#F150SR PEDO FORCEPS RAINBOW UPPER TOOTH
F150SSC	#150S Pedo Forceps, Seat. Children's
F150XAS	#150AS(X) Split Beak Pedo Forceps, Serr
F151	#151 Cryer Forceps
F151A	#151A Cryer Forceps
F151AS	#151AS Split Beak Forceps, Serrated
F151IS	151 Lower Universal, IS Forceps
F151K	#151 Forceps Small Pedo
F151S	#151S Pedo Forceps
F151SR	#F151SR PEDO FORCEPS RAINBOW LOWER TOOTH
F151SSC	#151S Pedo Forceps, Seat. Children's
F151XAS	#151AS(X) Split Beak Pedo Forceps, Serr
F16	#16 Forceps
F16M	#16 Forceps, Straight Handle
F16S	#16S Pedo Forceps
F17	#17 Forceps
F18L	#18L Harris Forceps
F18R	#18R Harris Forceps
F1IS	1 Upper Anterior, IS Forceps
F1S	#1 STANDARD PEDO FORCEPS
F1XS	1 Atraumair Standard Forceps, Upper Inci
F203	3#203 Forceps
F210H	#210H Forceps
F210S	#210S Forceps



F217	#217 Hu-Friedy Forceps
F222	#222 Forceps
F23	#23 Forceps
F23K	#23 Cowhorn Forceps Small Pedo
F23S	#23 COWHORN PEDO FORCEPS
F23XS	23 Atraumair Cowhorn Forceps, Lower Mola
F24	#24 Forceps
F286	#286 Forceps
F300	#300 Hu-Friedy Root Forceps, Serrated
F301	#301 Hu-Friedy Root Forceps, Serrated
F32	#32 Parmly Alveolar Forceps
F32A	#32A Parmly Forceps
F35XS	35 Atraumair Forceps, Upper Can/Premolar
F36XS	36 Atraumair Forceps, Lower Incisors
F39	#39 Pedo Forceps
F3FS	#3FS Woodward Forceps
F40	#40 Pedo Forceps
F53L	#53L Forceps
F53LIS	53L Upper Molar, Left, IS Forceps
F53R	#53R Forceps
F62	#62 Forceps
F65	#65 Forceps
F67XS	67 Atraumair Forceps, Upper Molars
F69	#69 Tomes Forceps
F69IS	69 Tomes Upper/Lower Roots, IS Forceps
F7077K	#23 Forceps Custom
F88L	#88L Nevius Forceps
F88LIS	88L Nevius Upper Molar, Right, IS Frcps
F88R	#88R Nevius Forceps
F88RIS	88R Nevius Upper Molar, Right, IS Frcps
F89	#89 Cook Forceps



F90	#90 Cook Forceps
F99C	#99C Kells Forceps
FAF1	Apical Forceps 1
FAF150	Apical Forceps 150
FAF151	Apical Forceps 151
FAF151IS	151 Lower Universal, Apical, IS Forceps
FAF1IS	1 Upper Anterior, Apical, IS Forceps
FAF1XS	1 Atraumair Apical Forceps, Upper Inciso
FAF222	Apical Forceps 222
FAF222IS	222 Lower Molars, Apical, IS Forceps
FAF35XS	35 Atraumair Apical Forceps, Upper Can/P
FAF36XS	36 Atraumair Apical Forceps, Lowr Prem/I
FAFX67A	Apical Forceps X67A
FAFX74N	Apical Forceps X74N
FMD1	MD-1 Mead Forceps, Serrated
FMD2	MD-2 Mead Forceps, Serrated
FMD3	MD-3 Mead Forceps, Serrated
FMD4	MD-4 Mead Forceps, Serrated
FX1	#1 European Style Forceps
FX13	#13 European Style Serrated Forceps
FX13E	#13 European Style Forceps
FX17	#17 European Style Forceps
FX17E	#17 European Style Forceps
FX18	#18 European Style Forceps, Serrated
FX18E	#18 European Style Forceps
FX1CE	HFE FORCEPS-CHILD (KNURLED HANDLE)
FX1E	#1 European Style Forceps
FX2	HFE #2 FORCEPS
FX22	#22 European Style Forceps
FX22E	#22 European Style Forceps
FX233	#233 Forceps, Serrated



FX233E	#233 Forceps, Serrated
FX2CE	HFE FORCEPS-CHILD (KNURLED HANDLE)
FX2E	#2 FORCEPS European
FX30E	HFE #30 FORCEPS
FX31E	HFE #31 FORCEPS
FX33	#33 European Style Forceps, Serrated
FX33E	#33 European Style Forceps, Serrated
FX34E	HFE #34 FORCEPS, MATTE FINISH
FX35E	HFE #35 FORCEPS, MATTE FINISH
FX36E	HFE #36 FORCEPS, MATTE FINISH
FX3CE	HFE FORCEPS-CHILD (KNURLED HANDLE)
FX44XS	44 Root Forceps
FX45XS	45 Atraumair Root Forceps, Serr., Lower
FX46L	#46L Root Forceps, Serrated
FX46LE	#46L Root Forceps, Serrated
FX49	#49 Forceps, Serrated
FX49E	#49 Forceps, Serrated
FX4CE	HFE FORCEPS-CHILD (KNURLED HANDLE)
FX4E	#4 FORCEPS European
FX51	#51 European Style Forceps, Serrated
FX51E	#51 European Style Forceps, Serrated
FX51XS	51 Atraumair Root Forceps, Serr., Upper
FX5CE	EUROPEAN FORCEPS-CHILD (KNURLED HANDLE)
FX67A	#67A European Style Forceps, Serrated
FX67AE	#67A European Style Forceps, Serrated
FX6CE	HFE FORCEPS-CHILD (KNURLED HANDLE)
FX7	7 European Style Forceps
FX73	#73 European Style Forceps, Serrated
FX73E	#73 European Style Forceps, Serrated
FX73XS	73 Atraumair Forceps, Lower Molars
FX74	#74 European Style Forceps, Serrated



FX74E	#74 European Style Forceps, Serrated
FX74N	#74N European Style Forceps, Serrated
FX74NE	#74N European Style Forceps, Serrated
FX76NE	Forceps #76NE Europ.IM narrow roots
FX76S	#76S Upper Root Forceps, Serrated
FX76SE	#76S Upper Root Forceps, Serrated
FX79	#79 European Style Forceps, Serrated
FX79CE	HFE #79 FORCEPS
FX79E	#79 European Style Forceps, Serrated
FX79XS	79 Atraumair Forceps, Lower Molars
FX7CE	HFE FORCEP-CHILD (KNURLED HDL)
FX7E	#7 European Style Forceps
FX86AE	HFE #86A FORCEPS
FX87E	HFE #87 FORCEPS
FX89E	HFE #89 FORCEPS
FX8E	HFE #8 FORCEPS
FX90E	HFE #90 FORCEPS
FX97	#97 Root Forceps, Serrated
FX97E	#97 Root Forceps, Serrated
H1	#1 Kelly Hemostat - Straight
H2	#2 Kelly Hemostat - Curved
H3	#3 Mosquito Hemostat - Curved
H4	#4 Mosquito Hemostat - Straight
H5	#5 Hemostat (1x2)
HAC	Adson Hemostat 7.5in Curved
HAS	Adson Hemostat 7.5in Straight
HHC	Hartmann Hemostat 4in Curved
HHS	Hartmann Hemostat 4in Straight
HKC	Kocher Hemostat 5.5in Curved
HKRC	Kelly-Rankin Hemostat 6.25 in Curved
HKRS	Kelly-Rankin Hemostat 6.5in Straight



HRPC	Rochester-Penn Hemostat Curved
NH5020	Perma Sharp Castro Needle Holder, Str.
NH5020M	Perm Sharp Mic Castro Needle Holder, Str
NH5020R	Perma Sharp Castro Needle Holder, Rnd
NH5021	Perma Sharp Castro Needle Holder, Crvd
NH5021M	Perm Sharp Mic Castro Needle Holder,Crvd
NH5021RC	Perm Sharp Castro Needle Holder, Crv Rnd
NH5022	Arruga Perma Sharp Needle Holder
NH5024	Perma Sharp Castro Needle Holder, Flat
NH5024CORT	Perma Sharp Cort. Castro Needle Holder
NH5024R	Perma Sharp Castro Needle Holder, Rnd
NH5024RC	Perm Sharp Castro Needle Holder, Rd, Crv
NH5024SIM	Needle Holder Simion
NH5030	Webster Perma Sharp Needle Holder
NH5032	Derf Perma Sharp Needle Holder
NH5034	Perma Sharp Hegar-Baumgar. Needle Holder
NH5036	Halsey Perma Sharp Needle Holder, Smooth
NH5037	Perma Sharp Halsey Needle Holder, Serr.
NH5038	Crile-Wood Perma Sharp Needle Holder
NH5038L	Perm Sharp CW Needle Holder Left Handed
NH5042	Mayo-Hegar Perma Sharp Needle Holder
NH5044	Perma Sharp Mayo-Hegar Needle Holder
NH5046	DE Bakey Perma Sharp Needle Holder
NH5050	HMT Perma Sharp Needle Holder
NH5052	FSP Perma Sharp Needle Holder
NH5052L	NADELHALTER FINE SWEDISH PATT. FÖR LINKS
NH5068	Perm Sharp Ols-Heg Needle Holder 6.75in
NH5072	Perm Sharp Ols-Heg Needle Holder 5.5in
NH5074	Mathieu-Kocher Perma Sharp Needle Holder
NH5074E	MATHIEU-KOCHER NEEDLE HOLDER
NH5076	Mathieu Perma Sharp Needle Holder



NH5082	Vascular Perma Sharp Needle Holder 6
NH5084	Vascular Perma Sharp Needle Holder 7 in
NH5092	Mini-Ryder Perma Sharp Needle Holder 6
NH5094	Mini-Ryder Perma Sharp Needle Holder 7
NHB	Boynton (HF) Needle Holder
NHC	Collier Needle Holder
NHCV	Castroviejo Needle Holder
NHCV18	Castroviejo Needle Holder, 18cm
NHCW	Crile-Wood Needle Holder
NHD	Derf Needle Holder
NHDCPV	Di Dust Castro Needle Holder Crv 6.0-8.0
NHDCPVN	Di Dust Castro Needle Holder Crv 4.0-6.0
NHDPV	MICROSURGICAL NEEDLE HOLDER/STEEL
NHDPVN	Diam. Dust. Castro Needle Holder 4.0-6.0
NHGILFINE	Gillies Fine Needle Holder
NHHB	Hegar-Baumgartner Needle Holder. 5-1/2in
NHLBPSB	Perma Sharp Lichtenberg Needle Holder
NHLBPSE	Perma Sharp Lichtenberg Needle Holder
NHM	Mathieu Needle Holder
NHM-5025R	Perma Sharp Castro Needle Holder Rnd 5in
NHM-5026R	Perma Sharp Mic Castro Needle Holder Rnd
NHM-5027	Micro Curved Castroviejo Needle Holder
NHM-5028	Micro Straight Castroviejo Needle Holder
NHMH	Mayo-Hegar Needle Holder
NHOH	Olsen-Hegar Needle Holder./Sciss Comb.
NHSLHUSM	Micro Castro Dia Dust NH 8-0-12-0
NHLSCHLEE	Schlee Microsurgical Needle Holder
NHSSL	Needleh/Scissors Sinusline str.6-0/8-0
NHTMBH	MICROSURGICAL NEEDLE HOLDER TITAN
NHTN18PS	TOENIS, PERMA SHARP NEEDLE HOLDER
NHW	Webster Needle Holder



NIPRO	Sugarman Nipro Tissue Nipper
NIPS	Small G/F Nipper
R1	#1 Hu-Friedy Rongeurs
R15	#15 Hu-Friedy Rongeurs
R18	#18 Hu-Friedy Rongeurs
R18M	Rongeur 18cm with Transmission
R1A	#1A Mead Rongeurs
R3H	#3H Dean Rongeurs
R4	#4 Cleveland Rongeurs
R4A	#4A Cleveland Rongeurs
R5	#5 Rongeur
R5S	#5S Cleveland Rongeurs
RBEY	Beyer Rongeurs
RBL	30 Std Blumenthal Rongeurs
RBL45	45 Blumenthal Rongeurs
RBL90	90 Blumenthal Rongeurs
RBOE	Boehler Rongeurs
RBOEC	Boehler Rongeurs, 15cm
RBOEE	Boehler Rongeurs
RF	Friedman Rongeurs
RF45	Steiglitz Root Forceps - 45 Deg.
RF90	Steiglitz Root Forceps - 90
RFP	Peet Silver Point Root Forceps
RFSTR	Steiglitz Root Forceps - Straight
RKN	Kramer-Nevins Rongeurs
RKSN	Short Nose, Rongeur
RMF	Friedman Rongeurs-Mini
RMF90	Friedman Rongeurs-Mini 90
S1	#1 Kelly Scissors, Curved
S10	#10 (25G) Scissors
S10SC	#10 Scissors Super Cut



S11	#11 Locklin Scissors
S12	#12 Locklin Scissors
S13	#13 Suture Scissors
S13S	#13S Suture Scissors
S14	#14 LaGrange Scissors
S14SC	B2-21cissors Super Cut
S14SCX	LaGrange Dbl-Crd, SC Scissors Black Line
S15	#15 Sullivan Scissors
S16	#16 Goldman-Fox Scissors
S16SC	#16 G-F Scissors Super Cut
S16SCX	Gold. Fox, Curv, SC Scissors Black Line
S17	#17 Iris Scissors, Straight
S17SC	Iris Super Cut Str Scissors
S17SCX	Iris, Straight, SC Scissors, Black Line
S18	#18 Iris Scissors, Curved
S18SC	Iris Super Cut Curved Scissors
S18SCX	Iris, Curved, SC Scissors, Black Line
S19SCX	Metzenbaum, SC Scissors, Black Line
S1L	#1L Kelly Scissors 7in Curved
S2	#2 Kelly Scissors, Straight
S20SCX	Gold. Fox, Strt, SC Scissors, Black Line
S21	#21 Surgical Scissors, S/Straight
S22	#22 Surgical Scissors, B/Straight
S23	#23 Surgical Scissors, S/Curved
S2L	#2L Kelly Scissors 7in Straight
S3	#3 Mayo Scissors, Curved
S31	#31 Castroviejo Scissors
S4	#4 Mayo Scissors, Straight
S40	Strabismus Scissors 4in Straight
S41	Strabismus Scissors 4in Curved
S5	#5 Wagner Scissors, Straight



S5001	Kelly Perma Sharp Scissors 6.25 Curved
S5002	Kelly Perma Sharp Scissors 6.25" Str.
S5009	Dean Perma Sharp Scissors 6.25
S5011	Locklin Perma Sharp Scissors Open Shank
S5012	Locklin Perma Sharp Scissors Clsd Shank
S5054	Metzenbaum Perma Sharp Scissors St/Bl
S5055	Metzenbaum Perma Sharp Scissors Cv/Bl
S5056	Metzenbaum Perma Sharp Scissors St/Pt
S5057	Metzenbaum Perma Sharp Scissors Cv/Pt
S5069	Metzenbaum Perma Sharp Scissors Cv/Del
S5080	GF Perma Sharp Scissors Straight
S5081	GF Perma Sharp Scissors Curved
S5082	Iris Perma Sharp Scissors Straight
S5083	Iris Perma Sharp Scissors Curved
S5095	Wire Cutting Perma Sharp Scissors
S6	#6 Wagner Scissors, Curved
S7	#7 Wagner Scissors, Angled
S8	#8 Quinby Scissors
S9	#9 Dean Scissors
SCGC	Crown & Gold Scissors, Curved
SCGCP	Crown & Gold Curved, Scissors, Pedo
SCGS	Crown & Gold Scissors, Straight
SCORT	Scissors Cortellini, 12 cm, curved
SCORTSC	SCISSORS CORTELLINI, 12CM, CRVD,SUPERCUT
SJC	Joseph Scissors Curved
SJS	Joseph Scissors Straight
SLB	Lister Bandage Scissors
SMB	Baby Metzenbaum Scissors
SPNHDPVN	Microsurg. Needle Holder Swiss Perio
SPSPV	Microsurgical Scissors, Swiss Perio
SPSPV45	Microsurg. Scissors, Swiss Perio 45 deg



SPV	MICROSURGICAL SCISSORS
SPVX	Castro Microsurgical,Black Line Scissors
STMBH	MICROSURGICAL SCISSORS/TITAN
TFB	Allison Baby Tissue Forceps
TFS	Allison Tissue Forceps, Straight
TP43A	Adson-Brown Tissue Forceps Angled
F13XSD	13 Atraumair Forceps, Lower Premolars, Diamond Dusted
F1XSD	1 Atraumair Standard Forceps, Upper Incisors, Diamond Dusted
F35XSD	35 Atraumair Forceps, Upper Canine/Premolars, Diamond Dusted
F36XSD	36 Atraumair Forceps, Lower Incisors, Diamond Dusted
F67XSD	67 Atraumair Forceps, Upper Molars, Diamond Dusted
FAF1XSD	1 Atraumair Apical Forceps, Upper Incisors, Diamond Dusted
FAF35XSD	35 Atraumair Apical Forceps, Upper Canines/Premolars, Diamond Dusted
FAF36XSD	36 Atraumair Apical Forceps, Lower Premolars/Incisors, Diamond Dusted
FX45XSD	45 Atraumair Root Forceps, Serrated, Lower, Diamond Dusted
FX51XSD	51 Atraumair Forceps, Serrated, Upper, Diamond Dusted
FX73XSD	73 Atraumair Forceps, Lower Molars, Diamond Dusted
FX79XSD	79 Atraumair Forceps, Lower Molars, Diamond Dusted
F222IS	Forceps Atlas, Lower Molar
F23IS	Forceps Atlas, Cowhorn
F53RIS	Forceps Atlas #53R, Upper Molar
FAF150IS	Forceps Atlas, Apical, Upper Universal
F21XS	Forceps #21 Atraumair, Serrated, 1st and 2nd lower molars
F21XSD	217 Atraumair Forceps, Diamond Dusted
FX44XSD	44 Atraumair Root Forceps, Diamond Dusted