



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:	0889950Hold1H4
Intended Purpose:	Nonsurgical instruments to hold or retract oral tissue or materials during a dental procedure.

meet 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, AAMI Pb70

Signature: Kimberly Ball

Title: Regulatory Affairs Specialist

Place of Issue: Chicago, IL USA

Date of Issue: June 28, 2023



Attachment 1: Part Code List

Partno	Description
1-015	Mini Blade Scalpel Handle
10-100-04E	#4 Scalpel Handle
10-130-03	#3 Scalpel Handle
10-130-03E	#3 Scalpel Handle
10-130-05	#5 Scalpel Handle, Round Straight
10-130-05A	#5 Scalpel Handle, Round
10-130-05D	#5 Scalpel Handle, Double, 1.5mm
10-130-05E	SCALPEL HANDLE NO. 5
10-130-07	#7 Scalpel Handle
10-130-07E	#7 Scalpel Handle
10-130-07K	#7K Scalpel Handle
10-130-08	Mini Scalpel Handle ResinEight
10-130-5AE	SKALPELLKLINGENHALTER #05 GEWINKELT
10-130-5DE	SKALPELLKLINGENHAL SINUS 5D 1,5MM DOPPEL
10-130-5EM	No 5 European Style Matte Scalpel Handle
10-130-70	#7 MINI SCALPEL BLADE HOLDER
10-130-7KE	#7K Scalpel Handle
10-199-00	Scalpel Blade Remover
1013005D1	#5 Scalpel Handle, Double, 1mm
124-001	Mirror Handle - European Thread
124-002	Mirror Handle - Cone Socket
125-001	Dressing Pliers Utility
125-002	#18 Dressing Pliers
145-001	Articulating Paper Forceps
145-002	Matrix holder Toffelmeier universal
159-001	Scalpel Handle #3
23689	Amalgam Carrier SE Regular
8773SERR	16T Serrated Cotton Pliers
AC5101	CF(R)II Amalgam Carrier SE Mini
AC5102	CF(R)II Amalgam Carrier SE Reg
AC5103	CF(R)II Amalgam Carrier SE Large
AC5103R	RECONDITIONED AC5103, SE
AC5201	CF(R)II Amalgam Carrier DE Regular/Mini
AC5201R	RECONDITIONED AC5201, DE
AC5202	CF(R)II Amalgam Carrier DE Regular/Large
AC5202R	RECONDITIONED AC5202, DE
AC5203	CF(R)II Amalgam Carrier DE Regular/Jumbo
AC5203R	RECONDITIONED AC5203, DE
AC5301	CF(R)II Amalgam Carrier SE Distal Mini
AC5302	CF(R)II Amalgam Carrier SE Distal Reg



APF2	Articulating Paper Forceps
APF2E	Articulating Paper Forceps
CRB	Bishop Cheek Retractor
CRBL	Black Cheek Retractor
CRC	Retractor Columbia Cheek
CRLABANCA	Labanca Malleable Retractors, Set of 3
CRM	Retractor U of Minnesota
CRM2	Cawood-Minnesota Retractor
CRMS	Cheek Retractor Simion
CRMT	Modified Serrated Minnesota Retractor
CRMX	Retractor U of Minn. Black Line
CRO1	Cheek Retractor Orringer #1
CRO2	Orringer #2 Cheek Retractor, Medium
CRO3	Orringer #3 Cheek Retractor, Large
CRPA	Plastic Retractors-Adult (Pair)
CRPC	Plastic Retractors-Child (Pair)
CRQ	Univ of ACTA Cheek Retractor
CRSA	Shuman Retractor-Adult
CRURBAN	Urban Cheek Retractor
CRW1	Weider Cheek & Tongue Retractor-Small
CRW2	Weider Cheek & Tongue Retractor-Large
DP1	#1 Dressing Pliers (Perry)
DP17	#17 Dressing Pliers
DP18	#18 Dressing Pliers
DP18JS-II	DP18 DRESSING PLIER, MORITA
DP18L	#18L Dressing Pliers (Locking)
DP18PS	#18 DRESSING PLIERS, PERMA SHARP
DP19	#19 Dressing Pliers
DP2	#2 Dressing Pliers (College)
DP2USC	USC #2 DRESSING PLIERS
DP3	#3 Dressing Pliers
DP317	#317 Dressing Pliers, Smooth Beak
DP318	#318 Foil Dressing Plier Meriam,Serrated
DP4	#4 Dressing Pliers
DPU17	Dressing Pliers, Utility Pick-Up
EPL1	#1 Endo Dressing Pliers (Locking)
EPL1NL	#1 ENDO "NON-LOCKING" PLIERS
GRK1	Kincheloe Retractor
GRM1	#1 Meinershagen Gingival Retractor
GRM2	#2 Meinershagen Gingival Retractor
GRM3	#3 Meinershagen Gingival Retractor
GRM4	#4 Meinershagen Gingival Retractor
HCB1	#1 Composite Brush Handle
IMPHDL6	Implacare Scaler - Satin Steel Handle
KPQ	Paquette Palatal Knife
M4C	#4 SS FS Simple Stem Mouth Mirror, 12



M4DC	#4 Mirror, double EU-Thread 6pcs/pack
M5C	#5 SS FS Simple Stem Mouth Mirror, 12
M5DC	#5 DS FS Simple Stem Mouth Mirror, 6
M7H	1-1/2in Exam Mirror w/Handle
M8H	2in- Exam Mirror w/Handle
MH0175E	SE CS MIRROR HANDLE-METRIC
MH1	#1 Cone Socket Mirror Handle
MH24	#24 Cone Socket Mirror Handle
MH24-4	MH24 HANDLE W/MIR4 MIRROR HEAD
MH24-5	MH24 HANDLE W/MIR5 MIRROR HEAD
MH24-5DS	MH24 HDL W/MIR5DS MIRROR HEAD
MH6	Cone Socket Mirror Handle, Satin Steel
MH6692K	#1 MIRROR HANDLE W/MM CALIBRATIONS
MH6B	Cone Socket Mirror Handle, Black
MH7	#7 Cone Socket Mirror Handle
MH7V	#7 Cone Socket Mirror Handle, Blue
MH8	Cone Socket Mirror Handle, ResinEight
MHE6	European Mirror Handle, Satin Steel
MHE6B	European Mirror Handle, Black
MHE6CH	European Mirror Handle, Smooth Satin Ste
MHE6M	European Mirror HdI Matte Cone Satin Stl
MHE71	European Mirror Handle, #7 HdI, Gray
MIR3HD	#3 HD CS Mirror SS, 1 EA
MIR3HDE	#3 HD Mirror, Simple Stem, 1 EA
MIR4	#4 FS CS Mirror, Single Sided, Single
MIR4/12	#4 FS CS Mouth Mirror, Dozen
MIR4/3	#4 FS CS Mouth Mirror, 3 pack
MIR4DS	#4 DS FS CS Mirror, Double Sided, Single
MIR4DS/3	#4 DS FS CS Mouth Mirror, 3 pack
MIR4DS/6	#4 DS FS CS MOUTH MIRROR, 6
MIR4DSHD	#4 HD CS Mirror DS, 1 EA
MIR4DSHD6	#4 HD CS Mirror DS, Six Pack
MIR4DSHD6E	#4 HD Mirror DS, Simple Stem, 6 Pack
MIR4DSHDE	#4 HD Mirror DS, Simple Stem,1 EA
MIR4HD	#4 HD CS Mirror SS, 1 EA
MIR4HD12	#4 HD CS Mirror SS, Dozen
MIR4HD12E	#4 HD Mirror, Simple Stem, Dozen
MIR4HD3	#4 HD CS Mirror SS, Three Pack
MIR4HD3E	#4 HD Mirror, Simple Stem, Three Pack
MIR4HDE	#4 HD Mirror, Simple Stem,1 EA
MIR4M	#4 FSCS MOUTH MIRROR U OF MD
MIR5	#5 FS CS Mirror, Single Sided, Single
MIR5/12	#5 FS CS Mouth Mirror, Dozen
MIR5/3	#5 FS CS Mouth Mirror, 3 pack
MIR5DS	#5 DS FS CS Mirror, Double Sided, Single
MIR5DS/3	#5 DS FS CS Mouth Mirror, 3 pack



MIR5DS/6	#5 DS FS CS Mouth Mirror, 6
MIR5DSHD	#5 HD CS Mirror DS, 1 EA
MIR5DSHD6	#5 HD CS Mirror DS, Six Pack
MIR5DSHD6E	#5 HD Mirror DS, Simple Stem, Six Pack
MIR5DSHDB	#5 HD CS Mirror DS, 1 EA, Black
MIR5DSHDBE	#5 HD SS Mirror DS, 1 EA, Black
MIR5DSHDE	#5 HD Mirror DS, Simple Stem, 1 EA
MIR5HD	#5 HD CS Mirror SS, 1 EA
MIR5HD12	#5 HD CS Mirror SS, Dozen
MIR5HD12E	#5 HD Mirror, Simple Stem, Dozen
MIR5HD3	#5 HD CS Mirror SS, Three Pack
MIR5HD3E	#5 HD Mirror, Simple Stem, Three Pack
MIR5HDB	#5 HD Mirror, Cone Socket, 1 EA, Black
MIR5HDBE	#5 HD Mirror, Simple Stem, 1 EA, Black
MIR5HDE	#5 HD Mirror, Simple Stem, 1 EA
MM1	Small Rectangular Micro Mirror
MM2	Med Rectangular Micro Mirror
MM3	Large Rectangular Micro Mirror
MM4	Micro Mirror Round 3.0mm
MM5	Micro Mirror Round 5.0mm
MM7	Micro Mirror 7mm x 2mm
MM8	Micro Mirror 9mm x 3mm
MMR	Large Round Micro Mirror
MMRS	Small Round Micro Mirror
MMVEL1	#1 Velvart Endo Satin Steel Micro Mirror
MMVEL2	#2 Velvart Endo Satin Steel Micro Mirror
MP48	Markel Mouth Prop Sm. (Child) Pair
MP52	Markel Mouth Prop (Child Pair)
MP54	Markel Mouth Prop (Adult Pair)
PCUPM	Pumice Cup Hu-Friedy Immunity
PFIWDS27	# 2 WOODSON DE PFI # 7 HDL
PMGF1	GF-1 Pocket Marker (Left)
PMGF2	GF-2 Pocket Marker (Right)
RDAF6	Rubber Dam Frame, Adult
RDAF6C	Rubber Dam Frame, Adult
RDC209	Rubber Dam Clamp #209
RDCACTA1	UNI.ACTA Rubber Dam Clamp #1 RDCM 8U67
RDCF5	Rubber Dam Frame, Child
RDCF5C	Rubber Dam Frame, Child
RDCM0	Rubber Dam Clamp #0, Satin Steel
RDCM00	Rubber Dam Clamp #00, Satin Steel
RDCM00X	Rubber Dam Clamp #00, Black Line
RDCM0X	Rubber Dam Clamp #0, Black Line
RDCM1	Rubber Dam Clamp #1, Satin Steel
RDCM10	Rubber Dam Clamp #10, Satin Steel
RDCM10X	Rubber Dam Clamp #10, Black Line



RDCM11	Rubber Dam Clamp #11, Satin Steel
RDCM11X	Rubber Dam Clamp #11, Black Line
RDCM12A	Rubber Dam Clamp #12A, Satin Steel
RDCM12A-G	Rubber Dam Clamp #12A-WITH GROOVES
RDCM12AX	Rubber Dam Clamp #12A, Black Line
RDCM13A	Rubber Dam Clamp #13A, Satin Steel
RDCM13A-G	Rubber Dam Clamp #13A-WITH GROOVES
RDCM13AX	Rubber Dam Clamp #13A, Black Line
RDCM14	Rubber Dam Clamp #14, Satin Steel
RDCM14A	Rubber Dam Clamp #14A, Satin Steel
RDCM14AX	Rubber Dam Clamp #14A, Black Line
RDCM14X	Rubber Dam Clamp #14, Black Line
RDCM18	Rubber Dam Clamp #18, Satin Steel
RDCM18X	Rubber Dam Clamp #18, Black Line
RDCM1A	Rubber Dam Clamp #1A, Satin Steel
RDCM1AX	Rubber Dam Clamp #1A, Black Line
RDCM1X	Rubber Dam Clamp #1, Black Line
RDCM2	Rubber Dam Clamp #2, Satin Steel
RDCM2-G	Rubber Dam Clamp #2-WITH GROOVES
RDCM201	Rubber Dam Clamp #201, Satin Steel
RDCM201X	Rubber Dam Clamp #201, Black Line
RDCM205	Rubber Dam Clamp #205, Satin Steel
RDCM205X	Rubber Dam Clamp #205, Black Line
RDCM209	Rubber Dam Clamp #209, Satin Steel
RDCM209X	Rubber Dam Clamp #209, Black Line
RDCM212	Rubber Dam Clamp #212, Satin Steel
RDCM212S	Rubber Dam Clamp #212 SOFT, SATIN STEEL
RDCM212SA	Rubber Dam Clamps #212SA anterior
RDCM212SAX	Rubber Dam Clamp #212SA, Black Line
RDCM212UN C	Rubber Dam Clamp #212UNC, Satin Steel
RDCM212X	Rubber Dam Clamp #212, Black Line
RDCM22	Rubber Dam Clamp #22, Satin Steel
RDCM24	Rubber Dam Clamp #24, Satin Steel
RDCM24X	Rubber Dam Clamp #24, Black Line
RDCM25	Rubber Dam Clamp #25, Satin Steel
RDCM25X	Rubber Dam Clamp #25, Black Line
RDCM26	Rubber Dam Clamp #26, Satin Steel
RDCM26N	Rubber Dam Clamp #26N, Satin Steel
RDCM26NM	Rubber Dam Clamp #26NM Satin Steel
RDCM26NX	Rubber Dam Clamp #26N, Black Line
RDCM26X	Rubber Dam Clamp #26, Black Line
RDCM27	Rubber Dam Clamp #27, Satin Steel
RDCM27N	Rubber Dam Clamp #27N, Satin Steel
RDCM27NX	Rubber Dam Clamp #27N, Black Line
RDCM27X	Rubber Dam Clamp #27, Black Line



RDCM28	Rubber Dam Clamp #28, Satin Steel
RDCM28X	Rubber Dam Clamp #28, Black Line
RDCM29	Rubber Dam Clamp #29, Satin Steel
RDCM29X	Rubber Dam Clamp #29, Black Line
RDCM2A	Rubber Dam Clamp #2A, Satin Steel
RDCM2A-G	Rubber Dam Clamp #2A-WITH GROOVES
RDCM2AS	Rubber Dam Clamp #2AS, Satin Steel
RDCM2ASX	Rubber Dam Clamp #2AS, Black Line
RDCM2AX	Rubber Dam Clamp #2A, Black Line
RDCM2X	Rubber Dam Clamp #2, Black Line
RDCM3	Rubber Dam Clamp #3, Satin Steel
RDCM3-G	Rubber Dam Clamp #3-WITH GROOVES
RDCM30	Rubber Dam Clamp #30, Satin Steel
RDCM30X	Rubber Dam Clamp #30, Black Line
RDCM31	Rubber Dam Clamp #31, Satin Steel
RDCM31X	Rubber Dam Clamp #31, Black Line
RDCM32	Rubber Dam Clamp #32, Small
RDCM32X	Rubber Dam Clamp #32, Black Line
RDCM33	Rubber Dam Clamp #33, Large
RDCM33X	Rubber Dam Clamp #33, Black Line
RDCM3X	Rubber Dam Clamp #3, Black Line
RDCM4	Rubber Dam Clamp #4, Satin Steel
RDCM4X	Rubber Dam Clamp #4, Black Line
RDCM5	Rubber Dam Clamp #5, Satin Steel
RDCM56	Rubber Dam Clamp #56, Satin Steel
RDCM56S	Rubber Dam Clamp #56S, Satin Steel
RDCM56SX	Rubber Dam Clamp #56S, Black Line
RDCM56X	Rubber Dam Clamp #56, Black Line
RDCM5X	Rubber Dam Clamp #5, Black Line
RDCM6	Rubber Dam Clamp #6, Satin Steel
RDCM6X	Rubber Dam Clamp #6, Black Line
RDCM7	Rubber Dam Clamp #7, Satin Steel
RDCM7A	Rubber Dam Clamp #7A, Satin Steel
RDCM7AX	Rubber Dam Clamp #7A, Black Line
RDCM7X	Rubber Dam Clamp #7, Black Line
RDCM8	Rubber Dam Clamp #8, Satin Steel
RDCM8A	Rubber Dam Clamp #8A, Satin Steel
RDCM8AD	Rubber Dam Clamp #8AD, Satin Steel
RDCM8ADX	Rubber Dam Clamp #8AD, Black Line
RDCM8AX	Rubber Dam Clamp #8A, Black Line
RDCM8X	Rubber Dam Clamp #8, Black Line
RDCM9	Rubber Dam Clamp #9, Satin Steel
RDCM9-G	Rubber Dam Clamp #9-WITH GROOVES
RDCM9S	Rubber Dam Clamp #9S, Satin Steel
RDCM9SX	Rubber Dam Clamp #9S, Black Line
RDCM9X	Rubber Dam Clamp #9, Black Line



RDCMW12A	Rubber Dam Clamp #12A, SATIN STEEL
RDCMW13A	Rubber Dam Clamp #W13A, SATIN STEEL
RDCMW14	Rubber Dam Clamp #W14, Satin Steel
RDCMW14A	Rubber Dam Clamp #W14A, Satin Steel
RDCMW14AX	Rubber Dam Clamp #W14A, Black Line
RDCMW2	Rubber Dam Clamp #W2, Satin Steel
RDCMW2A	Rubber Dam Clamp #W2A, Satin Steel
RDCMW2X	Rubber Dam Clamp #W2, Black Line
RDCMW3	Rubber Dam Clamp #W3, Satin Steel
RDCMW3X	Rubber Dam Clamp #W3, Black Line
RDCMW4	Rubber Dam Clamp #W4, Satin Steel
RDCMW4X	Rubber Dam Clamp #W4, Black Line
RDCMW56	Rubber Dam Clamp #W56, Satin Steel
RDCMW7	Rubber Dam Clamp #W7, Satin Steel
RDCMW7X	Rubber Dam Clamp #W7, Black Line
RDCMW8A	Rubber Dam Clamp #W8A, Satin Steel
RDCMW8ASA	Rubber Dam Clamp #W8A, San Antonio
RDCMW8AX	Rubber Dam Clamp #W8A, Black Line
RDCSET	Clamp, Rubber Dam Clamp Set
RDCSET-A	Custom Clamp, Rubber Dam Clamp Set
RDCSET-S	Custom Rubber Dam Clamp Set (Spanish)
RDCSET7	Clamp, Rubber Dam Clamp Set 7
RDKIT	Rubber Dam Clamp Kit
RDKIT2	Rubber Dam Kit #2
SRTA01	Retractor palatinal Allam wechselbar
SRTA02	Retractor mandibular Allam link Molar we
SRTA03	Retraktor mandibular Allam rechts Molar
SRTA04	Retractor universal Allam Molar Z#hne we
SRTA05	Retractor univer. Allam flacher Einsatz
SRTA06	Retractor maxillar Allam rechts/2. Molar
SRTA07	Retractor maxillar Allam links/2. Molar
SRTZ01	Zumstein Mirror Retractor 76x96mm
SRTZ02	Zumstein Lateral Mirror Retractor 40x83mm
SRTZ03	Zumstein Lateral Mirror Retractor 33x83mm
SRTZ04	Zumstein Nasal Spine Hook Retractor 72mm
SRTZ05	Zumstein Nasal Spine Hook Retractor 93mm
SRTZ06	Zumstein Nasal Spine Hook Retractor 75mm
SRTZ07	RETRACTOR CHIRURGIE WECHSEL VESTIBULUM-H
WA	Amalgam Well
10-100-04	Scalpel Handle #4
PROCLHDLS	Chu Gauges handle #6S
SHTMBH	Scalpel Handle Micro hdl #SinusLine Titan
SHDPV	Scalpel Handle Steel Microsurgical
RDCM106L	Rubber Dam Clamp, #106L, Satin Steel
RDCM106LX	Rubber Dam Clamp, #106L, Black Line
RDCM106R	Rubber Dam Clamp, #106R, Satin Steel



RDCM106RX	Rubber Dam Clamp #106R, Black Line
RDCMB4	Rubber Dam Clamp, #B4, Satin Steel
RDCMB4X	Rubber Dam Clamp, #B4, Black Line