



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 hold oral tissue or materials and is 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: Kimberly Ball

KIMBERLY BALL

Title: Regulatory Affairs Specialist

Place of Issue: Chicago, IL USA

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Attachment 1: Part Code List

Part Number	Description
158-031	Semkin-Taylor Plier #31
158-033	Pinzette #33 chirurg.1x2-gerade 12,5cm
8-905DD	HF Micro Tissue Pliers, Diamond Dust.
EP6794K	SPECIAL ENDO PLIER
IR	IMPLANTOLOGY RETRACTOR
RSMID1	MIDDELDORPF RETRACTOR, 17x14
RSMID2	Middeldorpf Retractor, 22 x 20
SGRT	Sinus Retractor
SP20	#20 Corn Suture Pliers
SP20SLEM	Micro Corn Suture Pliers, Diamond Dust.
SPM20	Micro Suture Pliers
SPTPDAPV	Microsurg. Pliers Anatom. Swiss Perio
SPTPDSSPV	Microsurg. Pliers Str. Steel Swiss Perio
SR1	#1 Surgical Retractor
SR2	#2 Surgical Retractor
SR29	#29 Nasal Spine Retractor
SR3	#3 Surgical Retractor
SR4	#4 Surgical Retractor
SR50	#50 Channel Retractor
SR6	#6 Surgical Retractor
SR7	#7 Surgical Retractor
SR8	#8 Surgical Retractor
SR9	#9 Ramus Retractor
SRC3M	Desmarres Chalazion Retractor Md
SRM10	SINUS RETRACTOR MISCH 10
SRM15	Sinus Retractor Misch 15
TP151X2	GILLES 1X2 15cm TISSUE PLIERS
TP16	#16 Hu-Friedy Tissue Pliers



TP31	Semkin-Taylor Tissue Pliers, Straight
TP32	#32 Semkin-Taylor Tissue Pliers, Curved
TP33	Semkin-Taylor Tissue Pliers, 1x2 Str.
TP34	#34 Semkin-Taylor Tissue Plier 1x2 Curved
TP41	#41 Adson Plain Tissue Pliers
TP42	#42 Adson 1x2 Tissue Pliers
TP43	#43 Adson-Brown Tissue Pliers
TP43A	Adson-Brown Tissue Forceps Angled
TP50	#50 Fox Tissue Pliers
TP5041	Adson Perma Sharp Tissue Pliers
TP5042	Adson 1x2 Perma Sharp Tissue Pliers
TP5043	Adson-Brown Perma Sharp Tissue Pliers
TP5050	Gerald Perma Sharp 7 Tissue Pliers
TP5051	Gerald 1x2 Perma Sharp 7" Tissue Pliers
TP5060	Cushing Perma Sharp 7 Tissue Pliers
TP5061	Perma Sharp Cush. Tissue Pliers, Angled
TP5062	Perma Sharp Cushing Bayon. Tissue Pliers
TP5070	General Perma Sharp 6 Tissue Pliers
TP5071	Perma Sharp General Tissue Pliers, 1x2
TP5072	Perma Sharp Tissue Pliers
TP5080	Potts-Smith Perma Sharp 7" Tissue Pliers
TP5081	Potts-Smith Perma Sharp 8" T. P.
TP5090	DeBakey Perma Sharp 6 Tissue Pliers
TP5091	DeBakey Perma Sharp 7.5" Tissue Pliers
TP50L	#50L Fox Tissue Pliers w/Lock
TPA	Tissue Plier 1x2 Curved Fine
TPA15	Adson 1x2 15cm Tissue Pliers
TPASTMBH	Titanium Micro Tissue Pliers, Straight
TPCSTMBH	MICROSURGICAL PLIER CURVED/TITAN
TPDAPV	Anatomic Microsurgical Tissue Pliers
TPDSCP	MICROSURGICAL PLIERS CURVED/STEEL



TPDSSPV	Microsurgical Tissue Pliers, Straight
TPG1	Gerald 7in Tissue Pliers, Str/Serr
TPG2	Gerald 7in Tissue Pliers, Cvd/Serr
TPG3	Gerald 1x2 7in Tissue Pliers Str.
TPG4	Gerald 7in Tissue Pliers 1x2 Cvd.
TPKN	K-N Tissue Pliers 1x2 Curved
TPMSA	Adson Micro 1x2 Tissue Pliers
TPR6	Russian 6in Tissue Pliers
TPR8	Russian 8in Tissue Pliers
TPSLASCHLE	Schlee Micro Tissue Pliers, Straight
TPSLCOCMN	Micro Cooley SinusLine Cvd Tissue Plier
TPSLCOSM	Micro Tissue Plier Stg 18cm
TPSLSSCHLE	Micro Schlee Tissue Pliers Straight 18cm
TPSSTMBH	Tissue Plier 1x2 Stg Dia Dust Titan
TRA2	#2 Austin Tissue Retractor
TRFB	Farabeuf Tissue Retractor Twin Set
TRH1	#1 Henahan Retractor
TRH2	#2 Henahan Retractor
TRH2/3	#2/3 Henahan DE Retractor
TRH3	#3 Henahan Retractor
TRJK	Jackson Tissue Retractor
TRMGRIF	RETRACTORGRIF MIKROCHIRURGIE
TRS5	#5 Senn Tissue Retractor
SRMALO	Malo Surgical Retractor
TRARENS1	#1 Arens Tissue Retractor, Anterior