



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: TBD
EU Representative Address/ SRN	Hu-Friedy Europe LLC & Co. KG Kleines Öschle 8 78532 Tuttlingen Germany SRN: TBD
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:

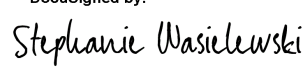
Product(s):	See attachment 1
REF:	See Attachment 1
Intended Purpose:	Instrument to place, transfer or condense oral tissue or materials and is used ultimately next to or in an artificially created orifice

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: Stephanie Wasielewski

DocuSigned by:

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Title: Director of Regulatory Affairs

Place of Issue: Chicago, IL USA

Date of Issue: 5/19/2021



Attachment 1: Part Code List

Part Number	Description
134-017	0.8mm/1.0mm DE Condensor
134-018	1.2mm/1.6mm DE Condensor
134-019	2.0mm/2.5mm DE Condensor
143-001	#0 SE Posterior Spreader
143-002	#D11 SE Root Canal Spreader
143-003	#D11T SE Root Canal Spreader
143-004	#D11TS SE Root Canal Spreader
143-005	#D11S SE Root Canal Spreader
143-006	ISO Spreader #30
143-007	ISO Spreader #40
143-008	ISO Spreader #50
143-009	ISO Spreader #60
23469	Porcelain Filling Instrument DE #1
BONT	Bone Tamper 7mm
BPACK	Bone Packer DE 6-8mm
CSEUWES6	Euwe Bone Scoop/Plugger, #6 Short Satin
GF20	#20 Gold Foil Condenser
GPHF	Hu-Friedy Gauze Packer
GPHF6	Gauze Packer
GPW	Wakefield Gauze Packer
IS	Aqua-Fix Irrigating Syringe
MAR-AAC.5	#.5 Abou-Rass Angulated Apical Condenser
MAR-AAC1	#1 Abou-Rass Angulated Apical Condenser
MAR-AAC1.5	#1.5 Abou-Rass Angultd Apical Condenser
MAR-AAC2	#2 Abou-Rass Angulated Apical Condenser
MAR-AAC3	#3 Abou-Rass Angulated Apical Condenser
MAR-SAC.5	#.5 Abou-Rass Straight Apical Condenser
MAR-SAC1	#1 Abou-Rass Straight Apical Condenser
MAR-SAC1.5	#1.5 Abou-Rass Straight Apical Condenser
MAR-SAC2	#2 Abou-Rass Straight Apical Condenser
MAR-SAC3	#3 Abou-Rass Straight Apical Condenser
MCBLL	Lg Micro-Condenser/Burnisher, Left
MCBLM	Med Micro-Condenser/Burnisher, Left
MCBLS	Sm Micro-Condenser/Burnisher, Left
MCBRL	Lg Micro-Condenser/Burnisher, Right
MCBRM	Med Micro-Condenser/Burnisher, Right
MCBRM6	MCBRM with #6 Handle
MCBRS	Sm Micro-Condenser/Burnisher, Right
MCBRS6	MCBRS with #6 Handle
MCBUL	Universal Micro-Condenser/Burnisher, Lg
MCBUL6	MCBUL with #6 Handle
MCBUM	Universal Micro-Condenser/Burnisher, Med
MCBUM6	MCBUM with #6 Handle
MCBUS	Universal Micro-Condenser/Burnisher, Sm



MCBUS6	MCBUS with #6 Handle
MRFL	Micro-Retro Filling Instrument, Left
MRFR	Micro-Retro Filling Instrument, Right
PLGGR1	GRISDALE BONE CONDENSER 8-10-13-15-18
PLGGR1S6	Grisdale Bone Condenser
PLGGR1X	Grisdale Bone Condenser, Black Line
PLGTAHM	TAHMASEB Sinus Lift Inst / Bone Plugger
PTISB	Bulb For Water Syringe
PTIST	Tip, Aqua-Fix Syringe
RCP5508	MAR-AAC1 with MCBL5
RCS00A	#00 SE Anterior Spreader
RCS00P	#00 SE Posterior Spreader
RCS0A	#0 SE Anterior Spreader
RCS0P	#0 SE Posterior Spreader
RCS25NT	#25NT SE Root Canal Spreader
RCS25SNT	#25SNT SE Root Canal Spreader
RCS3	#3 SE Root Canal Spreader
RCS30	ISO Spreader #30
RCS36	#3 SE Root Canal Spreader #6 HDLE
RCS3NT	#3NT SE Root Canal Spreader
RCS40	ISO Spreader #40
RCS40NT	#40NT SE Root Canal Spreader
RCS40SNT	#40SNT SE Root Canal Spreader
RCS50	ISO Spreader #50
RCS60	ISO Spreader #60
RCSD11	#D11 SE Root Canal Spreader
RCSD116	#D11 SE Root Canal Spreader #6 HDLE
RCSD11NT	#D11NT SE Root Canal Spreader
RCSD11S	#D11S SE Root Canal Spreader
RCSD11T	#D11T SE Root Canal Spreader
RCSD11T6	#D11T SE Root Canal Spreader, Satin Stl
RCSD11TNT	#D11TNT SE Root Canal Spreader
RCSD11TS	#D11TS SE Root Canal Spreader
RCSD11TSNT	D11TSNT SE Root Canal Spreader
RCSD11TSX	#D11TS SE Root Canal Spreader, BlackLine
RCSD11TX	#D11T SE Root Canal Spreader, Black Line
RCSD11X	#D11 SE Root Canal Spreader, Black Line
RCSGP1	#GP1 SE Root Canal Spreader
RCSGP16	#GP1 SE Root Canal Spreader #6 Handle
RCSGP1X	#GP1 SE Root Canal Spreader, Black Line
RCSGP2	#GP2 SE Root Canal Spreader
RCSGP2-0	#GP2-0 SE Root Canal Spreader
RCSGP3	#GP3 SE Root Canal Spreader
RCSGP36	#GP3 SE Root Canal Spreader HDL#6
RCSMA57	#MA57 SE Root Canal Spreader
RCSMA576	#MA57 SE Root Canal Spreader HDL #6
RCSMA57NT	#MA57NT SE Root Canal Spreader
RCSMA57X	#MA57 SE Root Canal Spreader, Black Line



RCSW1S	#1S Wakai SE Root Canal Spreader
RCSW2S	#2S Wakai SE Root Canal Spreader
SYBG	Syringe Bone Grafting 7mm
SYRA	Syringe Anesthetic Aspir A Style 1.8ml
SYRCW	Syringe Anesthetic Aspir CW Style 1.8ml
SYRCWA18	1.8ml syringe Metric & Imperial Thread
SYRCWA22	2.2ml Syringe Metric & Imperial Thread