



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:	0889950Kit1FZ
Intended Purpose:	Collection of different class I instruments

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

Signature: Kimberly Ball

Title: Regulatory Affairs Specialist

Place of Issue: Chicago, IL USA

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Attachment 1: Part Code List

Part Number	Description
678-403	ORTHOPLIER CASE W/INSTRUMENTS
ALLENBASIC	Allen Basic Kit
CHUSET	Chu's Aesthetic Gauges Set
ALLENKIT	Dr. Allen Oral Plastic Kit
BONEKIT	Bone Spreading Kit
ELKIT	Luxating Elevator Kit
EPTKITD	Luxating Hybrids Kit, DIN
EXC33L7	# 33L DE ENDO EXCAVATOR # 7 HDL
IMATRAEXT	Atraumatic Extraction Kit
IMBASPER	Basic Perio Kit
IMBGKIT	Bone Grafting Kit
IMCRESTKIT	Crestal Sinus Lift Kit
IMEDCROWN	Crown&Bridge Kit DIN
IMEDENDO	Endodontic Kit DIN
IMEDENDOMS	Endo Micro Surgical Kit DIN
IMEDEXAM	Exam Kit DIN
IMEDIMPLM	Implant Maintenance KIT DIN
IMEDMICROS	Microsurgical Kit DIN
IMEDPERIMPL	Perimplantitis KIT DIN
IMEDPERIO	Exam Perio Kit DIN
IMEDPROFIB	Profi Basic Kit DIN
IMEDPROPHYM	Prophy Maintenance Kit DIN
IMEDRDAM	Rubber Dam Kit DIN
IMEDRESTO	Total Restorative Kit DIN
IMEDROOTPL	Root Planing Kit DIN
IMEDSINUS	Surgical Implant & Sinus Lift Kit DIN
IMEDSURGB	Surgical Basic Kit DIN
IMEDSUTURE	Surgical Suture removal Kit DIN
IMMICSUR	Microsurgical Kit
IMNATREXTX	Atraumatic Extraction Kit, Black Line
IMPCKITII	Implant Maintenance Starter Kit
IMSLEIMAND	Sleiman Pluggers 5-Instrument Kit
IMVETHYGIENE	VET HYGIENE KIT
MALALL4KIT	MALO ALL-ON-4 SURGERY KIT
MALALL4KITDIN	MALO ALL-ON-4 SURGERY KIT, DIN
MASSKITDIN	Massironi Kit, DIN
PEPTAPEA	CLEAR TAPE 2" WIDE
PFIDDDIN	DIN CompoSculp Instrument Kit
PFIDDDIN8	DIN CompoSculp Instrument Kit #8 Hndl
PFIDDROLL	ROLLUP of CompoSculp Instruments
PFIDDROLL8	ROLLUP of CompoSculp Instruments #8



PRM-KIT-01	Periodontal & Restorative Kit
RESTOREITDIN	WeRestore.it Kit DIN
RESTOREITKIT	WeRestore.it Kit
SAB-SK2	See and Buy Hygiene Kit 2
SAB-XTS	XTS-Instruments Kit
TNFFCASS	Adhesthetics Theca by Federico Ferraris
TNKREJCIKIT	Prof. Dr. Ivo Krejci XTS Kit
TNPOSKIT	XTS POSTERIOR COMPOSITE INST KIT
EPTKIT	Luxating Hybrids Kit
IMPCMKIT1	Camlog Sinus Lift Kit
IMPCMKIT2	Camlog Ridge Augmentation Kit
IMPCMKIT3	Camlog Graft and Membrane Placement Kit
IMPCMKIT4	Camlog Basic Implant Kit
K-NKIT	Kramer-Nevins Perio Surgery Kit
LSFSCKIT	LEE SILVERSTEIN FLAP/SUTURE CLOSURE KIT
BIOKIT	Bio-Emulation Kit
BIOKITDIN	Bio-Emulation Kit DIN
TNTAMKITAKRO	Clarence Tam SkoolToolz Kit w/Akro-Flex
AKRO-CASS	Akro-Flex w/Signature 5-instr cassette
AKRO-INFIN	Akro-Flex w/Infinity 5-instr cassette
AKRO-DIN	Akro-Flex w/DIN 5-instr cassette
BPMEKIT	Berutti Pasqualini Micro Endo Kit
BPMEKITDIN	Berutti Pasqualini Micro Endo Kit DIN
BPEMEKIT	Berutti Pasqualini Esse Micro Endo Kit
BPEMEKITDIN	Berutti Pasqualini EsseMicroEndo Kit DIN
IMLINGKIT	Lingual Liberty Kit
E4DEKIT	Exam Kit E4D
TNFFDIN	Ferraris Adhesthetics Theca Kit
TNTAMKITDIN	StyleSkulpt Kit Dr Tam
AJSRKIT	Allen/Johnston Suture Removal Kit
PTIKIT	Int. Periotome Kit
SLKNKIT	Kramer-Nevins Sinus Lift Kit
SPKITDIN	Swiss Perio Kit
AKRO-DIN	
PMKITDIN	Pink Matters Full Kit, DIN
SJOVANKIT	Jovanovic Implant/Bone/Soft Tissue Kit
WANGGSKIT	Wang General Surgery Kit
URBANGSDIN	Dr. Istvan Urban General Surgery Kit,DIN
URBANSLDIN	Dr. Istvan Urban Sinus Lift Kit, DIN
RESTOREIT2DIN	WeRestore.it Kit DIN 2
RESTOREIT2KIT	WeRestore.it Kit 2