

CE declaration of conformity – Directive 93/42/EEC
Class IIa products

We

MAILLEFER INSTRUMENTS HOLDING Sàrl and its subsidiaries






(including the subsidiaries: Maillefer Instruments Trading sàrl, Maillefer Instruments Manufacturing sàrl, Maillefer Instruments Consulting sàrl)
Trading as Dentsply Maillefer

Chemin du Verger 3, CH-1338 Ballaigues / Switzerland

declare on our own responsibility that the following medical devices listed in enclosure F 711.208.E: **Reference List A41** (8 pages), version n°05.

Conform to the requirements of Council Directive 93/42/EEC and meet the Essential Requirements of Annex I. All devices are designed, manufactured, tested and released for sale in accordance with the technical documentation.

This declaration is based on the following data:

-  Technical documentation demonstrating the product conformity to the requirements of the directive.
-  The CE certificate n° **16708** of acceptance of the complete assurance system according to annex II **point 3**, of the directive 93/42/EEC.
-  Applied norms: Listed in **F711.208.E Reference List A41**
-  Notified body: G-MED-LNE, F-75724 Paris Cedex 15
-  Conformity assessment procedure: Annex II **point 3**, of the directive 93/42/EEC

Dentsply Maillefer's Division maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820, EN ISO 13485:2012, the European Union Council Directive 93/42/EEC, the Japanese PAL law.

Ballaigues, 28th March 2014

Management Representative



Luc ETIENNE

MAILLEFER INSTRUMENTS
HOLDING Sàrl

Encl.



Reference list

A41: OBL Family - 1

Edition : 05

Date: 18.03.2014

Signature :



Code: D: Displacement from other list / N: New reference / M: Modification / R: Removed

GMDN: Global Medical Device Nomenclature

REF: Maillefer reference number

S: sterile / M: measure

Code	REF	Proprietary Name	Intended use	GMDN #	GMDN definition	Rule	Class	S/M	Standards
D	A022C	Gutta-Percha-Points	These points are used to fill the root canals.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
D	A022E	Gutta-Percha-Points	These points are used to fill the root canals.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
D	A022F	Auxiliary Gutta-Percha-Points	These points are used to fill the root canals.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
D	A022G	Gutta-Percha-Points ISO Color-Coded	These points are used to fill the root canals.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
D	A022J	Absorbent Paper points ISO Color-Coded .04	To dry the root canal used with the Profile system .04.	38777	Absorbent point, dental	6	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A022K	Absorbent Paper points ISO Color-Coded .06	To dry the root canal used with the Profile system .06.	38777	Absorbent point, dental	6	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, EN 980, ISO 15223, EN 1041, ISO 10993-1
D	A022L	Auxiliary Gutta-Percha-Points	These points are used to fill the root canals.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
D	A022M	Gutta-Percha-Points ISO Color-Coded .04	These points are used to fill the root canals used with the Profile system.04.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
D	A022N	Gutta-Percha-Points ISO Color-Coded .06	These points are used to fill the root canals used with the Profile system.06.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664

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D	A022O	ProTaper Next Gutta-Percha Points	These points are used to fill the root canals during treatment with ProTaper Next system.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A022Q	ProTaper Next Paper Points	To dry the root canal.	38777	Absorbent point, dental	6	Ila	S	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A022R	Absorbent Paper points ISO Color-Coded	To dry the root canal.	38777	Absorbent point, dental	6	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A022T	Absorbent Paper Points 02 ISO Color-Coded	To dry the root canal.	38777	Absorbent point, dental	6	Ila	S	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A022W	Paper points for ProTaper Universal	To dry the root canal.	38777	Absorbent point, dental	6	Ila	S	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A022X	Gutta-Percha Points for ProTaper Universal	These points are used to fill the root canals used with the ProTaper system.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
R	A022Y	Gutta-Percha for GT	These points are used to fill the root canals used with the GT system.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
R	A022Z	Paper points for system GT	To dry the root canal used with the system GT.	38777	Absorbent point, dental	6	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A023Y	GT series X Gutta-Percha-Points	These points are used to fill the root canals used with the GT series X system.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664

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D	A023Z	GT series X Paper Points	To dry the root canal used with the system GT series X.	38777	Absorbent point, dental	6	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A024W	Paper points for WaveOne	To dry the root canal during treatment with wave one system.	38777	Absorbent point, dental	6	Ila	S	EN ISO 13485, ISO 14971, EN 1641, ISO 7551, ISO 15223, EN 1041, ISO 10993-1
D	A024X	WaveOne Gutta-Percha points	These points are used to fill the root canals during treatment with Wave one system.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0166	Thermafil Obturators	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0167	Thermafil obturators assorted posterior kit	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0168	Thermafil obturators assorted anterior kit	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0348	Thermafil Obturators	The points are used to fill the root canals. The Ref. A0348 is identical to the Ref. A0166, but it is packed per 30 pieces in place of 6 pieces.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
R	A0378	GT Hand Files	For manual preparation of the root canal.	31878	File, endodontic, hand-held	6-2nd hyphen	I	-	EN ISO 13485, ISO 14971, EN 1639, ISO 3630-1, ISO 10993-1, ISO 17664, ISO 15223-1, EN 1041
R	A0420	System GT Rotary Files	Engine driven instrument for root canal shaping.	40529	Rasp, endodontic, powered	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041

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R	A0421	GT Obturators	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
R	A0430	System GT Rotary Files	Engine driven instrument for root canal shaping.	40529	Rasp, endodontic, powered	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041
R	A0431	GT Obturators	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0435	System GT Accessory Files	Engine driven instrument for root canal shaping.	40529	Rasp, endodontic, powered	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041
R	A0436	System GT Obturators Accessory	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
R	A0440	System GT Rotary Files	Engine driven instrument for root canal shaping.	40529	Rasp, endodontic, powered	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041
R	A0441	GT Obturators	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0450	System GT Accessory Files	Engine driven instrument for root canal shaping.	40529	Rasp, endodontic, powered	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041
	A0451	System GT Obturators Accessory	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664

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Code	REF	Proprietary Name	Intended use	GMDN #	GMDN definition	Rule	Class	S/M	Standards
	A0470	System GT Accessory Files	Engine driven instrument for root canal shaping.	40529	Rasp, endodontic, powered	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041
R	A0471	System GT Obturators Accessory	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
R	A0480	System GT Rotary Files	Set for mechanical preparation of the root canal.	38442	Unclassified	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041
R	A0481	GT Obturators	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0485	System GT Accessory Files	Engine driven instrument for root canal shaping.	40529	Rasp, endodontic, powered	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 1797-1, ISO 3630-1 (part.), ISO 10993-1, ISO 17664, ISO 17665-1, ISO 15223-1, EN 1041
	A0486	System GT Obturators Accessory	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0521	GT Series X Obturator	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0531	GT Series X Obturator	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A0541	GT Series X Obturator	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664

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	A0620	ProUltra	Insert for use on handpieces driven by an ultrasonic generator.	38442	Unclassified	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1
	A0621	ProUltra	Insert for use on handpieces driven by an ultrasonic generator.	38442	Unclassified	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1
	A0630	ProUltra	Insert for use on handpieces driven by an ultrasonic generator.	38442	Unclassified	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1
	A0631	ProUltra	Insert for use on handpieces driven by an ultrasonic generator.	38442	Unclassified	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1
	A0640	ProUltra	Insert for use on handpieces driven by an ultrasonic generator.	38442	Unclassified	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1
	A0650	ProUltra	Insert for use on handpieces driven by an ultrasonic generator.	38442	Unclassified	6	Ila	-	EN ISO 13485, ISO 14971, EN 1639, ISO 22374, ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664, ISO 17665-1
	A0901	GLYDE® File Prep syringe kit	Lubricate removing debris with hypochlorite (syringes).	35970	Syringe, dental, irrigating	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041
	A0902	GLYDE® File Prep Intro Package	Lubricate removing debris with hypochlorite (syringes and tips).	35970	Syringe, dental, irrigating	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041
	A0903	GLYDE® File Prep Syringe Tips	Tips.	35210	Needle, blunt, single use	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041

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	A0904	GLYDE® File Prep Sample Pack	Lubricate removing debris with hypochlorite (syringes and tips).	35970	Syringe, dental, irrigating	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041
	A0905	GLYDE®doses pack	Lubricate removing debris with hypochlorite (syringes and tips).	35970	Syringe, dental, irrigating	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, ISO 10993, ISO 15223-1, EN 1041
R	A0906	DMS IV	Solvent of root canal filling materials from Eugenol	38442	Unclassified	7	Ila	-	EN ISO 13485, ISO 14971, EN 1641, EN 1041, ISO 10993, ISO 15223-1, ISO 8601
	A1032	X-SMART® Plus	Endodontic micromotor to drive endodontic instruments.	38347	Drill, dental, electrically powered handpiece	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1
	A1032-1	X-SMART® Plus Grant Program	Endodontic micromotor to drive endodontic instruments.	38347	Drill, dental, electrically powered handpiece	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1
	A1032-2	X-SMART® Plus Demo Case	Demo case intended for the use of Salesmen.	38347	Drill, dental, electrically powered handpiece	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1
	A1032-3	X-SMART® Plus, PROPEX® II, Thermanprep 2 Demo case	Demo case intended for the use of Salesmen.	38347	Drill, dental, electrically powered handpiece	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1
	A1033	X-SMART® Plus 6:1 Contra-angle	Contra-angle linked to a micromotor in which dental instruments are fitted	31823	Drill, dental, attachment	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1
	A1034-3	X-SMART® Plus Motor Handpiece	Endodontic micromotor to drive endodontic instruments.	38347	Drill, dental, electrically powered handpiece	9	Ila	-	EN ISO 13485, ISO 14971, EN 1640, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62304, EN 62366, , ISO 11498, ISO 15223-1, ISO 17664, ISO 17665-1, EN 1041, ISO 10993-1

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	A1411	Protaper Universal obturator F1-F5	These points are destined for root canal obturation.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664
	A1700	WAVEONE® obturators	Used to obture the root canal after treatment using Wave one system.	31872	Dental material, root filling, gutta-percha	8-1st hyphen	Ila	-	EN ISO 13485, ISO 14971, EN 1641, ISO 6877 (part.), ISO 15223-1, EN 1041, ISO 10993-1, ISO 17664