Document Detail

Type: 1000-TF_8_EUDOC
Document No.: 1000-TF_8_EUDOC_000146[7]
Title: A41_EU Declaration of Conformity
Comment
Status: CURRENT
Effective Date: 29-Aug-2017

Approvals

Role	Sign-off By	Sign-off Date
ENDODONTICS Product Compliance Manager	Grégory Thomas	29-Aug-2017 8:44 am GMT

EU Declaration of Conformity

We,

MAILLEFER INSTRUMENTS HOLDING Sàrl

(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 all medical devices listed in **Annex I** conform to the requirements of the following directive:

- **Directive 93/42/EEC** concerning medical devices.

This declaration is based on the following data:

- Technical documentation demonstrating the product conformity to the requirements of the directive(s) mentioned above.
- Applied norms: **List of Applicable Standards of Technical File "A41"**.
- For class IIa products: The EC Certificate n° **CE 670383** of acceptance of the complete assurance system according to conformity assessment procedure: **Annex II excluding section 4 of Directive 93/42/EEC**.
- Notified body: **BSI Assurance UK Ltd**, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 8PP.

MAILLEFER INSTRUMENTS HOLDING Sàrl maintains a quality management system that complies with the **US FDA 21 CFR Part 820**, **EN ISO 13485:2012**, **Japanese PMDL law and TGA Medical Device Regulations**. All devices are designed, manufactured, tested and released for sale in accordance with related technical documentation.

11/07/2017

MAILLEFER INSTRUMENTS HOLDING SARL CH 1338 BALLAIGUES CHEMIN DU VERGER 3

MAILLEFER INSTRUMENTS HOLDING Sàrl

Luc ETIENNE
Management Representative

This document contains confidential and/or proprietary information.
It may not be reproduced or disclosed without prior written approval.

EU Declaration of Conformity

Annex I: Product list

Product Ref.	Product designation	Intended use	GMDN code & designation	MDD Classification	Rule	Sterile Yes: S / No: -
A022Cxxxxxx00	Gutta-Percha Points	These points are used to fill the root canals	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Exxxxxx00	Gutta-Percha Points	These points are used to fill the root canals	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Fxxxxxx00	Gutta-Percha Auxiliary Points	These points are used to fill the root canals	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Gxxxxxx00	Gutta-Percha Points ISO Color-Coded	These points are used to fill the root canals	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Jxxxxxx00	Absorbent Paper Points ISO Color-Coded .04	To dry the root canal prepared with the PROFILE system .04	38777 – Endodontic paper point	IIa	6	-
A022Kxxxxxx00	Absorbent Paper Points ISO Color-Coded .06	To dry the root canal prepared with the PROFILE system .06	38777 – Endodontic paper point	IIa	6	-
A022Lxxxxxx00	Gutta-Percha Auxiliary Points	These points are used to fill the root canals	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Mxxxxxx00	Gutta-Percha Points ISO Color-Coded 4%	These points are used to fill the root canals prepared with the PROFILE system .04	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Nxxxxxx00	Gutta-Percha Points ISO Color-Coded 6%	These points are used to fill the root canals prepared with the PROFILE system .06	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Oxxxxxx00	PROTAPER NEXT Gutta-Percha Points	These points are used to fill the root canals during treatment with PROTAPER NEXT system	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A022Qxxxxxx00	PROTAPER NEXT Paper Points	To dry the root canals	38777 – Endodontic paper point	IIa	6	-

For Use By Affiliates of DENTSPLY SIRONA
This document contains confidential and/or proprietary information.
It may not be reproduced or disclosed without prior written approval.

EU Declaration of Conformity

A022Rxxxxxx00	Absorbent Paper Points ISO Color-Coded	To dry the root canals	38777 – Endodontic paper point	IIa	6	-
A022Txxxxxx00	Absorbent Paper Points .02 ISO Color-Coded	To dry the root canals	38777 – Endodontic paper point	IIa	6	-
A022Wxxxxxx00	PROTAPER UNIVERSAL Paper Points	To dry the root canals	38777 – Endodontic paper point	IIa	6	-
A022Xxxxxx00	PROTAPER UNIVERSAL Gutta-Percha Points	These points are used to fill the root canals during treatment with PROTAPER UNIVERSAL system	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A023Yxxxxxx00	GT series X Gutta-Percha Points	These points are used to fill the root canals prepared with the GT series X system	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A023Zxxxxxx00	GT series X Paper Points	To dry the root canals prepared with the GT series X system	38777 – Endodontic paper point	IIa	6	-
A024Wxxxxxx01	Paper Points for WAVEONE	To dry the root canals during treatment with WaveOne system	38777 – Endodontic paper point	IIa	6	-
A024Xxxxxx00	WAVEONE Gutta-Percha Points	These points are used to fill the root canals during treatment with WaveOne system	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0166xxxxxx00	THERMAFIL OBTURATORS	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0167xxxxxx00	THERMAFIL OBTURATORS Assorted Posterior Kit	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0168xxxxxx00	THERMAFIL OBTURATORS Assorted Anterior Kit	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-

This document contains confidential and/or proprietary information.
It may not be reproduced or disclosed without prior written approval.

EU Declaration of Conformity

A0348xxxxxx00	THERMAFIL OBTURATORS	These points are used to fill the root canals. Ref. A0348 is identical to Ref. A0166 but it is packed per 30 pces instead of 6 pces.	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0435xxxxxx00	System GT Accessory Files	Engine driven instrument for root canal shaping	40529 – Rotary endodontic rasp	IIa	6	-
A0450xxxxxx00	System GT Accessory Files	Engine driven instrument for root canal shaping	40529 – Rotary endodontic rasp	IIa	6	-
A0451xxxxxx00	System GT Obturators Accessory	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0470xxxxxx00	System GT Accessory Files	Engine driven instrument for root canal shaping	40529 – Rotary endodontic rasp	IIa	6	-
A0485xxxxxx00	System GT Accessory Files	Engine driven instrument for root canal shaping	40529 – Rotary endodontic rasp	IIa	6	-
A0486xxxxxx00	System GT Obturators Accessory	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0521xxxxxx00	GT Series X Obturator	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0531xxxxxx00	GT Series X Obturator	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0541xxxxxx00	GT Series X Obturator	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-
A0620xxxxxx00	ProUltra	Insert for use on handpieces driven by an ultrasonic generator	44908 – Ultrasonic dental scaling/debridement system handpiece tip, periodontal	IIa	6	-
A0621xxxxxx00	ProUltra	Insert for use on handpieces driven by an ultrasonic generator	44908 – Ultrasonic dental scaling/debridement system handpiece tip, periodontal	IIa	6	-
A0630xxxxxx00	ProUltra	Insert for use on handpieces driven by an ultrasonic generator	44908 – Ultrasonic dental scaling/debridement system handpiece tip, periodontal	IIa	6	-

For Use By Affiliates of DENTSPLY SIRONA
This document contains confidential and/or proprietary information.
It may not be reproduced or disclosed without prior written approval.

A0631xxxxxx00	ProUltra	Insert for use on handpieces driven by an ultrasonic generator	44908 – Ultrasonic dental scaling/debridement system handpiece tip, periodontal	IIa	6	-
A0640xxxxxx00	ProUltra	Insert for use on handpieces driven by an ultrasonic generator	44908 – Ultrasonic dental scaling/debridement system handpiece tip, periodontal	IIa	6	-
A0650xxxxxx00	ProUltra	Insert for use on handpieces driven by an ultrasonic generator	44908 – Ultrasonic dental scaling/debridement system handpiece tip, periodontal	IIa	6	-
A0901xxxxxx00	GLYDE File Prep Syringe Kit	Lubricate removing debris with hypochlorite (syringes)	35970 – Dental irrigation/aspiration syringe	IIa	6	-
A0902xxxxxx00	GLYDE File Prep Intro Package	Lubricate removing debris with hypochlorite (syringes and tips)	35970 – Dental irrigation/aspiration syringe	IIa	6	-
A0903xxxxxx00	GLYDE File Prep Syringe Tips	Tips	35210 – Exploratory blunt needle, single-use	IIa	6	-
A0904xxxxxx00	GLYDE File Prep Sample Pack	Lubricate removing debris with hypochlorite (syringes and tips)	35970 – Dental irrigation/aspiration syringe	IIa	6	-
A0905xxxxxx00	GLYDE doses pack	Lubricate removing debris with hypochlorite (syringes and tips)	35970 – Dental irrigation/aspiration syringe	IIa	6	-
A1032xxxxxxxx	X-SMART PLUS	Endodontic micromotor to drive endodontic instruments	38347 – Dental power tool system handpiece, line-powered	IIa	9	-
A1032xxxxx100	X-SMART PLUS Grant Program	Endodontic micromotor to drive endodontic instruments	38347 – Dental power tool system handpiece, line-powered	IIa	9	-
A1033xxxxxx00	X-SMART PLUS Contra-Angle 6:1	Contra-angle linked to a micromotor in wich dental instruments are fitted	31823 – Dental drilling system attachment	IIa	9	-
A1034xxxxx300	X-XMART PLUS Handpiece	Endodontic micromotor to drive endodontic instruments	38347 – Dental power tool system handpiece, line-powered	IIa	9	-
A1411xxxxxx00	PROTAPER UNIVERSAL Obturator	Intended to be used for root canal obturation	31872 – Natural gutta-percha	IIa	8-1st hyphen	-

For Use By Affiliates of DENTSPLY SIRONA
This document contains confidential and/or proprietary information.
It may not be reproduced or disclosed without prior written approval.

EU Declaration of Conformity

A1700xxxxxx00	WAVEONE Obturators	Intended to be used for root canal obturation after treatment using WaveOne system	31872 – Natural gutta-percha	IIa	8-1st hyphen	-

Document History:

Version	Date	Change Summary
07	31.05.2017	Update of the previous DoC (1450-RDT_Dec of Conf_A41) following to our Notified Body change (LNE GMED → BSI). The reference A024Wxxxxxx00 was annulled

For Use By Affiliates of DENTSPLY SIRONA
This document contains confidential and/or proprietary information.
It may not be reproduced or disclosed without prior written approval.

EU Declaration of Conformity

1 REFERENCE DOCUMENTS

N/A

2 REVISION HISTORY

Rev.	Author	Description of change	Reason	Training required	
				Yes	No
0	YRO	First emission of the template.	N/A	x	0
1	LTO	Addition of a column in the table Annex I + more details regarding the conformity assessment procedure according to each kind of MD classes.	To differentiate sterile and non-sterile products + to better identify conformity assessment procedures.	0	x