Document Detail

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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 "PROTAPER NEXT"**.
- 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.

12/07/2017

MAILLEFER INSTRUMENTS HOLDING SARL CH 1338 BALLAIGUES CHEMIN DU VERGER 3

MAILLEFER INSTRUMENTS HOLDIND Sàrl

Luc ETIENNE
Management Representative

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Annex I: Product list

Product Ref.	Product designation	Intended use	GMDN code & designation	MDD Classification	Rule	Sterile Yes: S / No: -
A0800xxxxxx03	PROTAPER NEXT	PROTAPER NEXT is an engine driven instrument for root canal shaping and cleaning	40529 – Rotary endodontic rasp	IIa	6	S
A0800xxx9Ax03	PROTAPER NEXT Assortment	PROTAPER NEXT is an engine driven instrument for root canal shaping and cleaning	40529 – Rotary endodontic rasp	IIa	6	S
A080021900A03	PROTAPER NEXT XA	PROTAPER NEXT XA is an accessory opener file used for preflaring the orifice, removing triangles of dentin, relocating the coronal aspect of a canal away from an external root concavity, and creating more shape as desired in order to improve radicular access when needed	40529 – Rotary endodontic rasp	IIa	6	S
A08022259D003	PROTAPER NEXT Free Sample	PROTAPER NEXT is an engine driven instrument for root canal shaping and cleaning	40529 – Rotary endodontic rasp	IIa	6	S
A0803xxxxxx03	PROTAPER NEXT	PROTAPER NEXT is an engine driven instrument for root canal shaping and cleaning	40529 – Rotary endodontic rasp	IIa	6	S

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A0803xxx9Ax03	PROTAPER NEXT Assortment	PROTAPER NEXT is an engine driven instrument for root canal shaping and cleaning	40529 – Rotary endodontic rasp	IIa	6	S
A080321900A03	PROTAPER NEXT XA	PROTAPER NEXT XA is an accessory opener file used for preflaring the orifice, removing triangles of dentin, relocating the coronal aspect of a canal away from an external root concavity, and creating more shape as desired in order to improve radicular access when needed	40529 – Rotary endodontic rasp	IIa	6	S

Document History:

Version	Date	Change Summary
02	31.05.2017	Update of the previous DoC (1450-RDT_Dec of Conf_PROTAPER NEXT) following to our Notified Body change (LNE GMED → BSI).

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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