

Document Detail

Type: 1000-TF_8_EUDOC
Document No.: 1000-TF_8_EUDOC_000173[9]
Title: Protaper Gold (RU, NiTi, Ro, MSA)_EU Declaration of Conformity
Comment:
Status: CURRENT
Effective Date: 07-Oct-2022

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
1450-Senior Quality Assurance Manager 1450-Senior Quality Assurance Manager	Frederic Mottier	07-Oct-2022 8:21 am	GMT

DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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Manufacturer:	Name of the site: Maillefer Instruments Holding Sàrl Address of the site: Chemin du Verger 3, CH-1338 Ballaigues, Switzerland Single registration number (SRN): CH-MF-000016301		
Authorized EU-representative:	Name of the site: Dentsply DeTrey GmbH Address of the site: De-Trey-Straße 1, 78467 Konstanz, Germany Single registration number (SRN): DE-AR-000005904		
Authorized UK-representative:	Name of the site: Dentsply IH Ltd. Address of the site: Building 3, The Heights, Weybridge KT13 0NY, United Kingdom		
PRODUCT CODE / CATALOGUE NUMBER	NAME	PRODUCT CODE / CATALOGUE NUMBER	NAME
A0409221G0103	PROTAPER GOLD® Sterile Files Assortment	A0411221G0303	PROTAPER GOLD Sterile Finishing Files
A0409225G0103	PROTAPER GOLD® Sterile Files Assortment	A0411221G0403	PROTAPER GOLD Sterile Finishing Files
A0409225GD103	PROTAPER GOLD DEMO PACK/Sterile Files Assortment	A0411221G0503	PROTAPER GOLD Sterile Finishing Files
A0409231G0103	PROTAPER GOLD® Sterile Files Assortment	A0411225G0103	PROTAPER GOLD Sterile Finishing Files
A0410219G0103	PROTAPER GOLD Sterile Shaping Files	A0411225G0203	PROTAPER GOLD Sterile Finishing Files
A0410221G0103	PROTAPER GOLD Sterile Shaping Files	A0411225G0303	PROTAPER GOLD Sterile Finishing Files
A0410221G0203	PROTAPER GOLD Sterile Shaping Files	A0411225G0403	PROTAPER GOLD Sterile Finishing Files
A0410225G0103	PROTAPER GOLD Sterile Shaping Files	A0411225G0503	PROTAPER GOLD Sterile Finishing Files
A0410225G0203	PROTAPER GOLD Sterile Shaping Files	A0411231G0103	PROTAPER GOLD Sterile Finishing Files
A0410231G0103	PROTAPER GOLD Sterile Shaping Files	A0411231G0203	PROTAPER GOLD Sterile Finishing Files
A0410231G0203	PROTAPER GOLD Sterile Shaping Files	A0411231G0303	PROTAPER GOLD Sterile Finishing Files
A0411221G0103	PROTAPER GOLD Sterile Finishing Files	A0411231G0403	PROTAPER GOLD Sterile Finishing Files
A0411221G0203	PROTAPER GOLD Sterile Finishing Files	A0411231G0503	PROTAPER GOLD Sterile Finishing Files
Classification and Rules (EU and UK)	EU class: IIa following Rule 6 ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: IIa following Rule 6 ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002		
Basic UDI-DI	++J00310031DQ		
EMDN code	L159004 - ENDODONTIC RASPATORIES AND FILES		
GMDN Code / description	40529 - Rotary/reciprocating endodontic file/rasp, reusable		
Intended purpose: Engine-driven instrument intended for root canal preparation (shaping and debridement of the root canal)			

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WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF

- THE REGULATION EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX CHAPTER I and III.
- THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478).

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

Common Standards applied:	N/A
Technical standards ref.:	1000-TF_1_LAS_000065
EC Certificate	EC certificate number: MDR 741027 Notified Body name: BSI Group The Netherlands B.V. Notified Body address: Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands Notified Body ID: CE 2797
UK Certificate	UK certificate number (valid to the date of issue): Not yet issued Notified Body name: BSI Assurance UK Ltd Notified Body address: Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom Notified Body ID: UKCA 0086
Reference to the corresponding Technical Documentation	Technical Documentation name: Protaper Gold (RU, NiTi, Ro, MSA) Technical Documentation Index: 1000-TF_0_TDI_000030
Expiration date for the DoC	Covered by the validity date of EC certificate.

Ballaigues, 12.09.2022

Frédéric Mottier
QA/RC Director of Maillefer Instruments Holding Sàrl.

FORM NO	8000-FM-008-05	REVISION LEVEL	3
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REVISION LEVEL	CC/CHO REFERENCE	PREPARED BY	DESCRIPTION OF CHANGE
9	Single approval	A. Vialichka	First DoC under new MDR CE Certificate 8000 template according to the EU MDR used for the first time Protaper Ultimate SKUs were moved to a dedicated DoC <i>Note: Refer to the previous DoC for a complete revision history</i>

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