

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
A0751225G9D03	WaveOne® Gold Reciprocating File Sterile	A0754225G9A03	WaveOne® Gold Assortment Reciprocating Files Sterile
A0753221G0L03	WaveOne® Gold Reciprocating Files Sterile	A0754231G9A03	WaveOne® Gold Assortment Reciprocating Files Sterile
A0753221G0M03	WaveOne® Gold Reciprocating Files Sterile	A0756221G0L03	WaveOne® Gold Reciprocating Files Sterile
A0753221G0P03	WaveOne® Gold Reciprocating Files Sterile	A0756221G0M03	WaveOne® Gold Reciprocating Files Sterile
A0753221G0S03	WaveOne® Gold Reciprocating Files Sterile	A0756221G0P03	WaveOne® Gold Reciprocating Files Sterile
A0753225G0L03	WaveOne® Gold Reciprocating Files Sterile	A0756221G0S03	WaveOne® Gold Reciprocating Files Sterile
A0753225G0M03	WaveOne® Gold Reciprocating Files Sterile	A0756225G0L03	WaveOne® Gold Reciprocating Files Sterile
A0753225G0P03	WaveOne® Gold Reciprocating Files Sterile	A0756225G0M03	WaveOne® Gold Reciprocating Files Sterile
A0753225G0S03	WaveOne® Gold Reciprocating Files Sterile	A0756225G0P03	WaveOne® Gold Reciprocating Files Sterile
A0753231G0L03	WaveOne® Gold Reciprocating Files Sterile	A0756225G0S03	WaveOne® Gold Reciprocating Files Sterile
A0753231G0M03	WaveOne® Gold Reciprocating Files Sterile	A0756231G0L03	WaveOne® Gold Reciprocating Files Sterile
A0753231G0P03	WaveOne® Gold Reciprocating Files Sterile	A0756231G0M03	WaveOne® Gold Reciprocating Files Sterile
A0753231G0S03	WaveOne® Gold Reciprocating Files Sterile	A0756231G0P03	WaveOne® Gold Reciprocating Files Sterile
A0754221G9A03	WaveOne® Gold Assortment Reciprocating Files Sterile	A0756231G0S03	WaveOne® Gold Reciprocating Files Sterile
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	++J00310039E8		
EMDN code	Q010507 - ENDODONTIC INSTRUMENTARY, SINGLE-USE (ENLARGERS, FILES, RASPS, ETC.)		
GMDN Code / description	63550 - Rotary/reciprocating endodontic file/rasp, single-use		
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: WaveOne Gold (SU, NiTi, Ro, MSA) Technical Documentation Index: 1000-TF_0_TDI_000065
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.

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