Dentsply Sirona

Document Detail

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Title: Protaper Next (SU, NiTi, Ro, MSA)_Declaration of Conformity

Comment:

Status: CURRENT

Effective Date: 07-Oct-2022

Approval

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

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
A080021900A03	ProTaper Next® Accessory File Sterile	**A080321900A03**	ProTaper Next® Accessory File Sterile
A080022100103	ProTaper Next® Shaping Files Sterile	**A080322100103**	ProTaper Next® Shaping Files Sterile
A080022100203	ProTaper Next® Shaping Files Sterile	**A080322100203**	ProTaper Next® Shaping Files Sterile
A080022100303	ProTaper Next® Shaping Files Sterile	**A080322100303**	ProTaper Next® Shaping Files Sterile
A080022100403	ProTaper Next® Shaping Files Sterile	**A080322100403**	ProTaper Next® Shaping Files Sterile
A080022100503	ProTaper Next® Shaping Files Sterile	**A080322100503**	ProTaper Next® Shaping Files Sterile
A08002219A003	ProTaper Next®	**A08032219A003**	ProTaper Next®
A080022500103	ProTaper Next® Shaping Files Sterile	**A080322500103**	ProTaper Next® Shaping Files Sterile
A080022500203	ProTaper Next® Shaping Files Sterile	**A080322500203**	ProTaper Next® Shaping Files Sterile
A080022500303	ProTaper Next® Shaping Files Sterile	**A080322500303**	ProTaper Next® Shaping Files Sterile
A080022500403	ProTaper Next® Shaping Files Sterile	**A080322500403**	ProTaper Next® Shaping Files Sterile
A080022500503	ProTaper Next® Shaping Files Sterile	**A080322500503**	ProTaper Next® Shaping Files Sterile
A08002259A003	ProTaper Next®	**A08032259A003**	ProTaper Next®
A080023100103	ProTaper Next® Shaping Files Sterile	**A080323100103**	ProTaper Next® Shaping Files Sterile
A080023100203	ProTaper Next® Shaping Files Sterile	**A080323100203**	ProTaper Next® Shaping Files Sterile
A080023100303	ProTaper Next® Shaping Files Sterile	**A080323100303**	ProTaper Next® Shaping Files Sterile
A080023100403	ProTaper Next® Shaping Files Sterile	**A080323100403**	ProTaper Next® Shaping Files Sterile
A080023100503	ProTaper Next® Shaping Files Sterile	**A080323100503**	ProTaper Next® Shaping Files Sterile
A08002319A003	ProTaper Next®	**A08032319A003**	ProTaper Next®
A08022259D003	ProTaper Next®		
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	**++J00310032DS**
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)**	
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 Next (SU, NiTi, Ro, MSA)** Technical Documentation Index: **1000-TF_0_TDI_000060**
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.

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 *Note: Refer to the previous DoC for a complete revision history*