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
A022X00010100	Protaper® Universal Gutta-Percha Points	A022X00090100	Protaper® Universal Gutta-Percha Points
A022X00010200	Protaper® Universal Gutta-Percha Points	A022X00090200	Protaper® Universal Gutta-Percha Points
A022X00010300	Protaper® Universal Gutta-Percha Points		

Classification and Rules (EU and UK)	EU class: **IIa** following **Rule 8** ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: **IIa** following **Rule 8** ACCORDING TO ANNEX IX OF THE EUROPEAN DIRECTIVE 93/42/EC AND UK MDR 2002
Basic UDI-DI:	**++J00310041DT**
EMDN code / description:	**Q01010203 / Dental cone**
GMDN code / description:	**45081 / Synthetic gutta-percha**
Intended purpose:	**Gutta-Percha Points are intended to fill the shaped, cleaned and irrigated root canal space.**

WE HEREWITH DECLARE, UNDER OUR SOLE RESPONSIBILITY, 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.

External references (Common Specifications, Standards, Regulations) applied	See List of Applicable Standards (see Technical Documentation Index for document number).
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** Certificate expiration date: **16.08.2027**
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** Certificate expiration date: **Not yet issued.**
Reference to the corresponding Technical Documentation	Technical Documentation name: **GPP (DS Brazil, MSA)** Technical Documentation Index: **1000-TF_0_TDI_000094**

Ballaigues, 10.10.2023

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