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
A024202102503	GUTTA-CONDENSOR Sterile	A024202502503	GUTTA-CONDENSOR Sterile
A024202103003	GUTTA-CONDENSOR Sterile	A024202503003	GUTTA-CONDENSOR Sterile
A024202103503	GUTTA-CONDENSOR Sterile	A024202503503	GUTTA-CONDENSOR Sterile
A024202104003	GUTTA-CONDENSOR Sterile	A024202504003	GUTTA-CONDENSOR Sterile
A024202104503	GUTTA-CONDENSOR Sterile	A024202504503	GUTTA-CONDENSOR Sterile
A024202105003	GUTTA-CONDENSOR Sterile	A024202505003	GUTTA-CONDENSOR Sterile
A024202105503	GUTTA-CONDENSOR Sterile	A024202505503	GUTTA-CONDENSOR Sterile
A024202106003	GUTTA-CONDENSOR Sterile	A024202506003	GUTTA-CONDENSOR Sterile
A024202107003	GUTTA-CONDENSOR Sterile	A024202507003	GUTTA-CONDENSOR Sterile
A024202108003	GUTTA-CONDENSOR Sterile	A024202508003	GUTTA-CONDENSOR 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 EUROPEAN DIRECTIVE 93/42/EC AND UK MDR 2002
Basic UDI-DI:	**++J00310049EB**
EMDN code / description:	**Q010507 / Endodontic instrumentary, single-use (enlargers, files, rasps, etc.)**
GMDN code / description:	**63622 / Endodontic obturation material distribution endpiece, single-use**
Intended purpose:	**Engine driven instrument intended for thermocompaction of Gutta-Percha points.**

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: **N/A**
Reference to the corresponding Technical Documentation	Technical Documentation name: **Gutta-condensor (MSA)** Technical Documentation Index: **1000-TF_0_TDI_000106**

Ballaigues, 22.09.2023

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

REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
0	Franck Boutet	First revision under MDR certification. Use of the new template 8000-FM-008-05. *Note1: Refer to the previous DoC (1000-TF_8_EUDOC_000160 [8]) for a complete revision history.* *Note2: Sterile and Non-sterile products are now split in 2 different DoC. See 1000-TF_8_EUDOC_000160 for non-sterile products.*