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
C010120000100	RS RADIX Penetration Drill	C021620000100	RADIX-ANKER-STANDARD
C010120000200	RS RADIX Penetration Drill	C021620000200	RADIX-ANKER-STANDARD
C010120000300	RS RADIX Penetration Drill	C021620000300	RADIX-ANKER-STANDARD
C010220000100	RS RADIX Precision Spiral Drill	C021620003B00	RADIX-ANKER-STANDARD
C010220000200	RS RADIX Precision Spiral Drill	C021720000100	RADIX-ANKER-STANDARD
C010220000300	RS RADIX Precision Spiral Drill	C021720000200	RADIX-ANKER-STANDARD
C021220000800	UNIMETRIC 0.8 MM Special penetration drill	C021720000300	RADIX-ANKER-STANDARD
C021220010800	UNIMETRIC 0.8 MM Special penetration drill	C021720003B00	RADIX-ANKER-STANDARD
C021220011000	UNIMETRIC 1 MM Special Penetration Drill	C022020000100	RADIX-ANKER-STANDARD
C021220020800	UNIMETRIC 0.8 MM Special penetration drill	C022020000200	RADIX-ANKER-STANDARD
C021220021000	UNIMETRIC 1 MM Special Penetration Drill	C022020000300	RADIX-ANKER-STANDARD
C021220030800	UNIMETRIC 0.8 MM Special penetration drill	C022020003B00	RADIX-ANKER-STANDARD
C021220031000	UNIMETRIC 1 MM Special Penetration Drill	C026320000100	RADIX-ANKER-LONG
C021320000800	UNIMETRIC 0.8 MM Special calibration drill	C026320000200	RADIX-ANKER-LONG
C021320010800	UNIMETRIC 0.8 MM Special calibration drill	C026320000300	RADIX-ANKER-LONG
C021320011000	UNIMETRIC 1 MM Special calibration drill	C060100000100	EASYPOST® Precision drill
C021320020800	UNIMETRIC 0.8 MM Special calibration drill	C060100000200	EASYPOST® Precision drill
C021320021000	UNIMETRIC 1 MM Special calibration drill	C060100000300	EASYPOST® Precision drill
C021320030800	UNIMETRIC 0.8 MM Special calibration drill	C060100000400	EASYPOST® Precision drill
C021320031000	UNIMETRIC 1 MM Special calibration drill	C060100000500	EASYPOST® Precision drill
C021420000000	UNIMETRIC Special Precalibrating Drill	C060100000600	EASYPOST® Precision drill

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:	**++J00310055E6**
EMDN code / description:	**Q010199 / Device for conservative dentistry and endodontics - others**
GMDN code / description:	**43311 / Pin-Post dental drill bit**
Intended purpose:	**Drills for Posts are devices used for the creation of hole for post placement.**

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 (certificate not yet issued).**
Reference to the corresponding Technical Documentation	Technical Documentation name: **Drills for Posts (MSA)** Technical Documentation Index: **1000-TF_0_TDI_000086**

Ballaigues, 14.11.2023

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

REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
3	Franck Boutet	First revision under MDR certification. Use of the new template 8000-FM-008-05. *Note: Refer to the previous DoC (1000-TF_8_EUDOC_000266 [2]) for a complete revision history.*