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
A016D02100804	ReadySteel® Hedstroem File	**A016D03101004**	Readysteel® Hedstroem File
A016D02101004	ReadySteel® Hedstroem File	**A016D03101504**	Readysteel® Hedstroem File
A016D02101504	ReadySteel® Hedstroem File	**A016D03102004**	Readysteel® Hedstroem File
A016D02102004	ReadySteel® Hedstroem File	**A016D03102504**	Readysteel® Hedstroem File
A016D02102504	ReadySteel® Hedstroem File	**A016D03103004**	Readysteel® Hedstroem File
A016D02103004	ReadySteel® Hedstroem File	**A016D03103504**	Readysteel® Hedstroem File
A016D02103504	ReadySteel® Hedstroem File	**A016D03104004**	Readysteel® Hedstroem File
A016D02104004	ReadySteel® Hedstroem File	**A016D03104504**	Readysteel® Hedstroem File
A016D02104504	ReadySteel® Hedstroem File	**A016D03105004**	Readysteel® Hedstroem File
A016D02105004	ReadySteel® Hedstroem File	**A016D03105504**	Readysteel® Hedstroem File
A016D02105504	ReadySteel® Hedstroem File	**A016D03106004**	Readysteel® Hedstroem File
A016D02106004	ReadySteel® Hedstroem File	**A016D03107004**	Readysteel® Hedstroem File
A016D02107004	ReadySteel® Hedstroem File	**A016D03108004**	Readysteel® Hedstroem File
A016D02108004	ReadySteel® Hedstroem File	**A016D03109004**	Readysteel® Hedstroem File
A016D02109004	ReadySteel® Hedstroem File	**A016D03110004**	Readysteel® Hedstroem File
A016D02110004	ReadySteel® Hedstroem File	**A016D03111004**	Readysteel® Hedstroem File
A016D02111004	ReadySteel® Hedstroem File	**A016D03112004**	Readysteel® Hedstroem File
A016D02112004	ReadySteel® Hedstroem File	**A016D03113004**	Readysteel® Hedstroem File
A016D02113004	ReadySteel® Hedstroem File	**A016D03114004**	Readysteel® Hedstroem File
A016D02114004	ReadySteel® Hedstroem File	**A016D03190004**	Readysteel® Hedstroem File
A016D02190004	ReadySteel® Hedstroem File	**A016D03190104**	Readysteel® Hedstroem File
A016D02190104	ReadySteel® Hedstroem File	**A016D03190204**	Readysteel® Hedstroem File
A016D02190204	ReadySteel® Hedstroem File	**A101602100804**	Readysteel® Senseus® Hedstroem
A016D02500804	Readysteel® Hedstroem File	**A101602101004**	Readysteel® Senseus® Hedstroem
A016D02501004	Readysteel® Hedstroem File	**A101602101504**	Readysteel® Senseus® Hedstroem
A016D02501504	Readysteel® Hedstroem File	**A101602102004**	Readysteel® Senseus® Hedstroem
A016D02502004	Readysteel® Hedstroem File	**A101602102504**	Readysteel® Senseus® Hedstroem
A016D02502504	Readysteel® Hedstroem File	**A101602103004**	Readysteel® Senseus® Hedstroem
A016D02503004	Readysteel® Hedstroem File	**A101602103504**	Readysteel® Senseus® Hedstroem

A016D02503504	Readysteel® Hedstroem File	**A101602104004**	Readysteel® Senseus® Hedstroem
A016D02504004	Readysteel® Hedstroem File	**A101602104504**	Readysteel® Senseus® Hedstroem
A016D02504504	Readysteel® Hedstroem File	**A101602105004**	Readysteel® Senseus® Hedstroem
A016D02505004	Readysteel® Hedstroem File	**A101602105504**	Readysteel® Senseus® Hedstroem
A016D02505504	Readysteel® Hedstroem File	**A101602106004**	Readysteel® Senseus® Hedstroem
A016D02506004	Readysteel® Hedstroem File	**A101602107004**	Readysteel® Senseus® Hedstroem
A016D02507004	Readysteel® Hedstroem File	**A101602108004**	Readysteel® Senseus® Hedstroem
A016D02508004	Readysteel® Hedstroem File	**A101602190004**	Readysteel® Senseus® Hedstroem
A016D02509004	Readysteel® Hedstroem File	**A101602190104**	Readysteel® Senseus® Hedstroem
A016D02510004	Readysteel® Hedstroem File	**A101602500804**	Readysteel® Senseus® Hedstroem
A016D02511004	Readysteel® Hedstroem File	**A101602501004**	Readysteel® Senseus® Hedstroem
A016D02512004	Readysteel® Hedstroem File	**A101602501504**	Readysteel® Senseus® Hedstroem
A016D02513004	Readysteel® Hedstroem File	**A101602502004**	Readysteel® Senseus® Hedstroem
A016D02514004	Readysteel® Hedstroem File	**A101602502504**	Readysteel® Senseus® Hedstroem
A016D02590004	Readysteel® Hedstroem File	**A101602503004**	Readysteel® Senseus® Hedstroem
A016D02590104	Readysteel® Hedstroem File	**A101602503504**	Readysteel® Senseus® Hedstroem
A016D02590204	Readysteel® Hedstroem File	**A101602504004**	Readysteel® Senseus® Hedstroem
A016D02800804	Readysteel® Hedstroem File	**A101602504504**	Readysteel® Senseus® Hedstroem
A016D02801004	Readysteel® Hedstroem File	**A101602505004**	Readysteel® Senseus® Hedstroem
A016D02801504	Readysteel® Hedstroem File	**A101602505504**	Readysteel® Senseus® Hedstroem
A016D02802004	Readysteel® Hedstroem File	**A101602506004**	Readysteel® Senseus® Hedstroem
A016D02802504	Readysteel® Hedstroem File	**A101602507004**	Readysteel® Senseus® Hedstroem
A016D02803004	Readysteel® Hedstroem File	**A101602508004**	Readysteel® Senseus® Hedstroem
A016D02803504	Readysteel® Hedstroem File	**A101602590004**	Readysteel® Senseus® Hedstroem
A016D02804004	Readysteel® Hedstroem File	**A101602590104**	Readysteel® Senseus® Hedstroem
A016D02804504	Readysteel® Hedstroem File	**A101603100804**	Readysteel® Senseus® Hedstroem
A016D02805004	Readysteel® Hedstroem File	**A101603101004**	Readysteel® Senseus® Hedstroem
A016D02805504	Readysteel® Hedstroem File	**A101603101504**	Readysteel® Senseus® Hedstroem
A016D02806004	Readysteel® Hedstroem File	**A101603102004**	Readysteel® Senseus® Hedstroem
A016D02807004	Readysteel® Hedstroem File	**A101603102504**	Readysteel® Senseus® Hedstroem

A016D02808004	Readysteel® Hedstroem File	**A101603103004**	Readysteel® Senseus® Hedstroem
A016D02809004	Readysteel® Hedstroem File	**A101603103504**	Readysteel® Senseus® Hedstroem
A016D02810004	Readysteel® Hedstroem File	**A101603104004**	Readysteel® Senseus® Hedstroem
A016D02811004	Readysteel® Hedstroem File	**A101603104504**	Readysteel® Senseus® Hedstroem
A016D02812004	Readysteel® Hedstroem File	**A101603105004**	Readysteel® Senseus® Hedstroem
A016D02813004	Readysteel® Hedstroem File	**A101603105504**	Readysteel® Senseus® Hedstroem
A016D02814004	Readysteel® Hedstroem File	**A101603106004**	Readysteel® Senseus® Hedstroem
A016D02890004	Readysteel® Hedstroem File	**A101603107004**	Readysteel® Senseus® Hedstroem
A016D02890104	Readysteel® Hedstroem File	**A101603108004**	Readysteel® Senseus® Hedstroem
A016D02890204	Readysteel® Hedstroem File	**A101603190004**	Readysteel® Senseus® Hedstroem
A016D03100804	Readysteel® Hedstroem File	**A101603190104**	Readysteel® Senseus® Hedstroem

Classification and Rules (EU and UK)	EU class: **Irs** following **Rule 6-2nd hyphen** ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: **Is** following **Rule 6-2nd hyphen** ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002
Basic UDI-DI	**++J00310003DK**
EMDN code	**L159004 - ENDODONTIC RASPATORIES AND FILES**
GMDN Code / description	**31878 - Manual endodontic file/rasp, reusable**
Intended purpose: **Manual 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: **Hedstroem files (RU, SST, Ma, MSA)** Technical Documentation Index: **1000-TF_0_TDI_000010**
Expiration date for the DoC	Covered by the validity date of EC certificate.

Ballaigues, 12.09.2022