See Annex I for translations / Voir « Annex I » pour les traductions / Se bilag I for oversættelse/ Siehe Anhang I für die Übersetzung/ Skatiet I pielikumu tulkošanai/ Zobacz załącznik I dla tłumaczenia/ Glej Prilogo I za prevod/ Çeviri için Ek I'e bakın

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: **Brunel Way,** **Stonehouse,** **Gloucestershire,** **GL10 3GB**

PRODUCT CODE / CATALOGUE NUMBER	NAME	PRODUCT CODE / CATALOGUE NUMBER	NAME
A011N21801503	ProFile® STERILE .04	A034422102003	ProFile® STERILE .02
A011N21802003	ProFile® STERILE .04	A034422102503	ProFile® STERILE .02
A011N21802503	ProFile® STERILE .04	A034422103003	ProFile® STERILE .02
A011N21803003	ProFile® STERILE .04	A034422104003	ProFile® STERILE .02
A011N21803503	ProFile® STERILE .04	A034422190003	ProFile® STERILE .02
A011N21804003	ProFile® STERILE .04	A034422501503	ProFile® STERILE .02
A011N21890003	ProFile® STERILE .04	A034422502003	ProFile® STERILE .02
A011N22101503	ProFile® STERILE .04	A034422502503	ProFile® STERILE .02
A011N22102003	ProFile® STERILE .04	A034422503003	ProFile® STERILE .02
A011N22102503	ProFile® STERILE .04	A034422503503	ProFile® STERILE .02
A011N22103003	ProFile® STERILE .04	A034422504003	ProFile® STERILE .02
A011N22103503	ProFile® STERILE .04	A034422590003	ProFile® STERILE .02
A011N22104003	ProFile® STERILE .04	A034521801503	ProFile® STERILE .06
A011N22104503	ProFile® STERILE .04	A034521802003	ProFile® STERILE .06
A011N22106003	ProFile® STERILE .04	A034521802503	ProFile® STERILE .06
A011N22109003	ProFile® STERILE .04	A034521803003	ProFile® STERILE .06
A011N22190003	ProFile® STERILE .04	A034521803503	ProFile® STERILE .06
A011N22190703	ProFile® STERILE .04	A034521804003	ProFile® STERILE .06
A011N22501503	ProFile® STERILE .04	A034521890003	ProFile® STERILE .06
A011N22502003	ProFile® STERILE .04	A034522101503	ProFile® STERILE .06
A011N22502503	ProFile® STERILE .04	A034522102003	ProFile® STERILE .06
A011N22503003	ProFile® STERILE .04	A034522102503	ProFile® STERILE .06
A011N22503503	ProFile® STERILE .04	A034522103003	ProFile® STERILE .06
A011N22504003	ProFile® STERILE .04	A034522103503	ProFile® STERILE .06
A011N22504503	ProFile® STERILE .04	A034522104003	ProFile® STERILE .06
A011N22506003	ProFile® STERILE .04	A034522190003	ProFile® STERILE .06
A011N22509003	ProFile® STERILE .04	A034522501503	ProFile® STERILE .06
A011N22590003	ProFile® STERILE .04	A034522502003	ProFile® STERILE .06
A011N22590703	ProFile® STERILE .04	A034522502503	ProFile® STERILE .06
A011N23101503	ProFile® STERILE .04	A034522503003	ProFile® STERILE .06
A011N23102003	ProFile® STERILE .04	A034522503503	ProFile® STERILE .06
A011N23102503	ProFile® STERILE .04	A034522504003	ProFile® STERILE .06
A011N23103003	ProFile® STERILE .04	A034522590003	ProFile® STERILE .06

A011N23103503	ProFile® STERILE .04	A035921900103	ProFile® STERILE O.S
A011N23104003	ProFile® STERILE .04	A035921900203	ProFile® STERILE O.S
A011N23104503	ProFile® STERILE .04	A035921900303	ProFile® STERILE O.S
A011N23109003	ProFile® STERILE .04	A035921900403	ProFile® STERILE O.S
A011N23190003	ProFile® STERILE .04	A035921900503	ProFile® STERILE O.S
A011N23190703	ProFile® STERILE .04	A035921900603	ProFile® STERILE O.S
A034422101503	ProFile® STERILE .02	A035921990003	ProFile® STERILE O.S

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 :	**++J00310028E3**
EMDN code / description :	**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, 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). - UKMDR2002: THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478) WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN UK MDR Part II Annex II Sec. 3.2 Full Quality System. 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: **Profile (SU, NiTi, Ro, MSA)** Technical Documentation Index: **1000-TF_0_TDI_000059**

Ballaigues, 06.01.2025

Signature



Frédéric Mottier
QA/Quality Compliance Director

REVISION HISTORY

(Can be removed while provided externally)

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
21	A.Vialichka	First revision under MDR certification. Use of the new template 8000-FM-008-05. Note: Refer to the previous DoCs for a complete revision history.
22	Marie Chantebel	Correction of typos in the product name: "®" was missing for certains SKUs.
23	Marie Chantebel	Template update. Update UK-Rep address following CHANGE-PLN-2024-561.

Annex I - Translation

Traduction / Oversættelse / Übersetzung / Tulkojums / Tłumaczenie / Prevajanje / Çeviri

EN	FR / DK / DE / LV / PL / SI / TR
Manufacturer	Fabricant / Producent / Hersteller / Ražotājs / Producent / Proizvajalec / Üretici
Name of the site	Nom du site / Stedets navn / Name des Standorts / Objekta nosaukums / Nazwa ośrodka / Naziv lokacije / Tesisin adı
Address of the site	Adresse du site / Stedets adresse / Anschrift des Standorts / Objekta adrese / Adres ośrodka / Naslov lokacije / Tesisin adresi
Single registration number (SRN)	Numéro d'enregistrement unique (SRN) / Individuelt registreringsnummer (SRN-nummer) / Einmalige Registrierungsnummer (SRN) / Vienotais reģistrācijas numurs (VRN) / Numer pojedynczej rejestracji (SRN) / Enotna registrska številka (SRN) / Tek kayıt numarası (SRN)
Authorized EU-representative	Représentant européen autorisé / Autoriseret EU-repræsentant / In der EU ansässiger Bevollmächtigter / Pilnvarotais pārstāvis ES / Autoryzowany przedstawiciel UE / Pooblaščeni predstavnik EU / Yetkili AB temsilcisi
Classification and Rules (EU)	Classification et Règles (UE) / Klassificering og regler (EU) / Klassifizierung und Regeln (EU) / Klasifikācija un noteikumi (ES) / Klasyfikacja i reguły (UE) / Razvrstitev in pravila (EU) / Sınıflandırma ve Kurallar (AB)
EU class	Classe de l'UE / EU-klasse / EU-Klasse / ES klase / Klasa UE / Razred EU / AB sınıfı:
ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745	CONFORMÉMENT À L'ANNEXE VIII DU RÈGLEMENT 2017/745 I HENHOLD TIL BILAG VIII TIL FORORDNING 2017/745 GEMÄSS ANHANG VIII DER VERORDNUNG 2017/745 SASKAŅĀ AR REGULAS 2017/745 VIII PIELIKUMU ZGODNIE Z ANEKSEM VIII DO ROZPORZĄDZENIA 2017/745 V SKLADU S PRILOGO VIII K UREDBI 2017/745 2017/745 SAYILI YÖNETMELİĞİN EK VIII'SİNE GÖRE
Basic UDI-DI	IUD-ID de base / Grundlæggende UDI-DI / Grundlegende UDI-DI/Pamata UDI-DI /Kod Basic UDI-DI/Osnovni UDI-DI/Temel UDI-DI
EMDN code - description	Code EMDN – Description / EMDN-kode - beskrivelse / EMDN-Code - Beschreibung / EMDN kods - apraksts / Kod EMDN - opis / EMDN koda - opis / EMDN kodu - açıklaması
GMDN code - description	Code GMDN - Description / GMDN-kode - beskrivelse / GMDN-Code - Beschreibung / GMDN kods - apraksts / Kod GMDN - opis / GMDN koda - opis / GMDN kodu - açıklaması
Intended purpose	Utilisation prévue / Tilsigtet anvendelse / Vorgesehener Verwendungszweck / Paredzētais nolūks / Przeznaczenie / Predvideni namen / Kullanım amacı
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. (or ANNEXE X or ANNEXE XI – precise chapters) ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	NOUS DÉCLARONS PAR LA PRÉSENTE, SOUS NOTRE SEULE RESPONSABILITÉ, QUE LES PRODUITS SUSMENTIONNÉS SATISFONT AUX DISPOSITIONS - DU RÈGLEMENT UE/2017/745 RELATIF AUX DISPOSITIFS MÉDICAUX, CONFORMÉMENT À LA PROCÉDURE D'ÉVALUATION DE LA CONFORMITÉ. TOUTES LES PIÈCES JUSTIFICATIVES SONT CONSERVÉES DANS LES LOCAUX DU FABRICANT. LE FABRICANT EST EXCLUSIVEMENT RESPONSABLE DE LA DÉCLARATION DE CONFORMITÉ.
	VI ERKLÆRER HERMED PÅ EGET ANSVAR, AT OVENNÆVNTE PRODUKTER OPFYLDER BESTEMMELSERNE I - FORORDNING EU/2017/745 OM MEDICINSK UDSTYR I OVERENSSTEMMELSE MED DEN OVERENSSTEMMELSESVURDERINGSPROCEDURE, DER ER BESKREVET. AL UNDERSTØTTENDE DOKUMENTATION OPBEVARES HOS PRODUCENTEN. PRODUCENTEN ER EKSKLUSIVT ANSVARLIG FOR OVERENSSTEMMELSESERKLÆRINGEN.
	WIR ERKLÄREN HIERMIT IN ALLEINIGER VERANTWORTUNG, DASS DIE OBEN GENANNTEN PRODUKTE DEN BESTIMMUNGEN DER - VERORDNUNG EU/2017/745 ÜBER MEDIZINPRODUKTE ENTSPRECHEN, GEMÄSS DEN VERFAHREN ZUR KONFORMITÄTSBEWERTUNG. ALLE UNTERSTÜTZENDEN DOKUMENTE WERDEN AM STANDORT DES HERSTELLERS AUFBEWAHRT. DIE VERANTWORTUNG FÜR DIE KONFORMITÄTSERKLÄRUNG LIEGT AUSSCHLIESSLICH BEIM HERSTELLER
	MĒS AR ŠO VIENĪGI UZ SAVU ATBILDĪBU APLIECINĀM, KA IEPRIEKŠ MINĒTIE RAŽOJUMI ATBILST NOTEIKUMIEM, KAS PAREDZĒTI - REGULĀ ES/2017/745, KAS ATTIECAS UZ MEDICĪNISKĀM IERĪCĒM, SASKAŅĀ AR ATBILSTĪBAS NOVĒRTĒŠANAS PROCEDŪRU. VISA APLIECINOŠĀ DOKUMENTĀCIJA TIEK GLABĀTA RAŽOTĀJA TELPĀS. PAR ATBILSTĪBAS DEKLARĀCIJU IR ATBILDĪGS TIKAI UN VIENĪGI RAŽOTĀJS.

	NA NASZĄ WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ NINIEJSZYM ZAŚWIADCZAMY, ŻE WYŻEJ WYMIENIONE PRODUKTY SPEŁNIAJĄ WYMAGANIA OKREŚLONE W POSTANOWIENIACH - ROZPORZĄDZENIA UE/2017/745 W SPRAWIE WYROBÓW MEDYCZNYCH ZGODNIE Z PROCEDURĄ OCENY ZGODNOŚCI. CAŁOŚĆ POWIĄZANEJ DOKUMENTACJI JEST PRZECHOWYWANA PRZEZ PRODUCENTA. WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ ZA DEKLARACJĘ ZGODNOŚCI PONOSI PRODUCENT.
	NA LASTNO ODGOVORNOST IZJAVLJAMO, DA ZGORAJ NAVEDENI IZDELKI IZPOLNJUJEJO DOLOČBE - UREDBA EU/2017/745 O ZDRAVSTVENIH PRIPOMOČKIH, V SKLADU S POSTOPKOM OCENJEVANJA SODOBNOSTI. VSO DOKAZNO DOKUMENTACIJO HRANI PROIZVAJALEC. ZA IZJAVO O SKLADNOSTI JE ODGOVOREN IZKLJUČNO PROIZVAJALEC.
	YUKARIDA BELİRTİLEN ÜRÜNLERİN AB/2017/745 SAYILI TIBBİ CİHAZLAR YÖNETMELİĞİ HÜKÜMLERİNE UYGUN OLDUĞUNU, - EKLERDE AÇIKLANAN UYGUNLUK DEĞERLENDİRME PROSEDÜRÜNE UYGUN OLARAK. TÜM DESTEKLEYİCİ BELGELER ÜRETİCİNİN TESİSLERİNDE SAKLANMAKTADIR. UYGUNLUK BEYANINDAN MÜNHASIRAN ÜRETİCİ SORUMLUDUR.
External references (Common Specifications, Standards, Regulations) applied	Références externes (Spécifications, Normes, Règlements communs) appliquées Anvendte eksterne referencer (fælles specifikationer, standarder, forordninger) Angewandte externe Referenzen (gemeinschaftliche Spezifikationen, Normen, Verordnungen) Piemērotās ārējās atsauces (kopējās specifikācijas, standarti, noteikumi) Zastosowane odniesienia zewnętrzne (wspólne specyfikacje, normy, rozporządzenia) Uporaba zunanjih referenc (skupne specifikacije, standardi, predpisi) Uygulanan dış referanslar (Ortak Şartnameler, Standartlar, Yönetmelikler)
EC Certificate	Certificat CE / EF-certifikat / EG-Zertifikat / EK sertifikāts / Certyfikat EC / Certifikat ES / EC Belgesi
EC certificate number	Numéro de certificat CE / EF-certifikatnummer / EG-Zertifikatsnummer / EK sertifikāta numurs / Numer certyfikatu EC / Številka certifikata ES / EC belge numarası
Notified Body name	Nom de l'Organisme notifié / Navn på bemyndiget organ / Benannte Stelle / Paziņotās iestādes nosaukums / Nazwa organu notyfikowanego / Naziv priglašenega organa / Onaylanmış Kuruluş adı
Notified Body address	Adresse de l'Organisme notifié / Det bemyndigede organs adresse / Anschrift der benannten Stelle / Paziņotās iestādes adrese / Adres organu notyfikowanego / Naslov priglašenega organa/ Onaylanmış Kuruluş adresi
Notified Body ID	Identifiant de l'Organisme notifié / Det bemyndigede organs id / Kennnummer der benannten Stelle / Paziņotā iestādes Nr / Identyfikator organu notyfikowanego / ID priglašenega organa / Onaylanmış Kuruluş Kimliği
Certificate expiration date	Date d'expiration du certificat /Certifikatets udløbsdato / Ablaufdatum des Zertifikats / Sertifikāta derīguma termiņš / Data ważności certyfikatu / Datum izteka veljavnosti potrdila / Belge son geçerlilik tarihi
Reference to the corresponding Technical Documentation	Référence à la Documentation Technique correspondante / Henvisning til den tilsvarende tekniske dokumentation / Verweis auf die entsprechende Technische Dokumentation / Atsauce uz attiecīgo tehnisko dokumentāciju / Odniesienie do odpowiedniej dokumentacji technicznej / Sklic na ustrezno tehnično dokumentacijo / İlgili Teknik Doküm antasyona Referans
Technical Documentation name	Nom de la Documentation Technique / Navn på teknisk dokumentation / Bezeichnung der Technischen Dokumentation / Tehniskās dokumentācijas nosaukums / Naziv tehnične dokumentacije
Technical Documentation Index	Index de la Documentation Technique / Indeks for teknisk documentation / Index der Technischen Dokumentation / Tehniskās dokumentācijas indekss / Nazwa dokumentacji technicznej / Indeks dokumentacji technicznej / Indeks tehnične dokumentacije / Teknik Dokümantasyon adı / Teknik Dokümantasyon Dizini