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
A016602502000	Thermafil® Obturators	A141100011200	ProTaper® Universal Obturators
A016602502500	Thermafil® Obturators	A141100011300	ProTaper® Universal Obturators
A016602503000	Thermafil® Obturators	A141100011400	ProTaper® Universal Obturators
A016602503500	Thermafil® Obturators	A141100011500	ProTaper® Universal Obturators
A016602504000	Thermafil® Obturators	A1411B0000100	Thermafil® for ProTaper Gold®
A016602504500	Thermafil® Obturators	A1411B0000200	Thermafil® for ProTaper Gold®
A016602505000	Thermafil® Obturators	A1411B0000300	Thermafil® for ProTaper Gold®
A016602505500	Thermafil® Obturators	A1411B0000400	Thermafil® for ProTaper Gold®
A016602506000	Thermafil® Obturators	A1411B0000500	Thermafil® for ProTaper Gold®
A016602507000	Thermafil® Obturators	A1411P0000100	Thermafil® for ProTaper Gold®
A016602508000	Thermafil® Obturators	A1411P0000200	Thermafil® for ProTaper Gold®
A016602509000	Thermafil® Obturators	A1411P0000300	Thermafil® for ProTaper Gold®
A016602510000	Thermafil® Obturators	A1411P0000400	Thermafil® for ProTaper Gold®
A016602511000	Thermafil® Obturators	A1411P0000500	Thermafil® for ProTaper Gold®
A016602512000	Thermafil® Obturators	A1750B0000L00	Thermafil® for WaveOne® Gold
A016602514000	Thermafil® Obturators	A1750B0000M00	Thermafil® for WaveOne® Gold
A016700090000	Thermafil® Obturators Assorted Posterior Kit	A1750B0000P00	Thermafil® for WaveOne® Gold
A016800090000	Thermafil® Obturators Assorted Anterior Kit	A1750B0000S00	Thermafil® for WaveOne® Gold
A034802502000	Thermafil® Obturators	A1750P0000L00	Thermafil® for WaveOne® Gold
A034802502500	Thermafil® Obturators	A1750P0000M00	Thermafil® for WaveOne® Gold
A034802503000	Thermafil® Obturators	A1750P0000P00	Thermafil® for WaveOne® Gold
A034802503500	Thermafil® Obturators	A1750P0000S00	Thermafil® for WaveOne® Gold
A034802504000	Thermafil® Obturators	DO-20	Domino Otturatori Endodontici per Mtwo
A141100010100	ProTaper® Universal Obturators	DO-25	Domino Otturatori Endodontici per Mtwo
A141100010200	ProTaper® Universal Obturators	DO-30	Domino Otturatori Endodontici per Mtwo
A141100010300	ProTaper® Universal Obturators	DO-35	Domino Otturatori Endodontici per Mtwo
A141100010400	ProTaper® Universal Obturators	DO-40	Domino Otturatori Endodontici per Mtwo
A141100010500	ProTaper® Universal Obturators	DO-45	Domino Otturatori Endodontici per Mtwo
A141100011100	ProTaper® Universal Obturators	-	-

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 :	**++J00310044DZ**

EMDN code / description :	**Q01010203 / Dental Cones**
GMDN code / description :	**47751 / Warm-bonded endodontic obturation system obturator**
Intended purpose:	**The devices 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). - 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: **Obturators (Plastic core, MSA)** Technical Documentation Index: **1000-TF_0_TDI_000098**

Ballaigues, 26.08.2025

Signature



Frédéric Mottier
QA / Quality Compliance Director

REVISION HISTORY

(Can be removed while provided externally)

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
7	Angélique Bolle-Maurin	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.
8	Aïssatou BAH	Update of Technical Document reference
9	Marie Chantebel	EMDN code alignment for all obturators group.
10	Marie Chantebel	Template update. Update UK-Rep address following CHANGE-PLN-2024-561.
11	Franck Boutet	Add new SKU (Elmo project): Thermafil® for ProTaper Gold® and Thermafil® for WaveOne® Gold.
12	Franck Boutet	Back to the equivalent of version 10 of this document, version 11 was released by mistake and was never used or shared.
13	Franck Boutet	Add new SKU (Elmo project): Thermafil® for ProTaper Gold® and Thermafil® for WaveOne® Gold.

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