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:<br>**Maillefer Instruments Holding Sàrl**<br>Address of the site:<br>**Chemin du Verger 3,**<br>**CH-1338 Ballaigues,**<br>**Switzerland**<br>Single registration number (SRN):<br>**CH-MF-000016301** | | |
| **Authorized EU-representative** | Name of the site:<br>**Dentsply DeTrey GmbH**<br>Address of the site:<br>**De-Trey-Straße 1,**<br>**78467 Konstanz,**<br>**Germany**<br>Single registration number (SRN):<br>**DE-AR-000005904** | | |
| **Authorized UK-representative** | Name of the site:<br>**Dentsply IH Limited**<br>Address of the site:<br>**Brunel Way, Stonehouse,**<br>**Gloucestershire, GL10 3GB,**<br>**United Kingdom** | | |
| **PRODUCT CODE / CATALOGUE NUMBER** | **NAME** | **PRODUCT CODE / CATALOGUE NUMBER** | **NAME** |
| **A0409221G0103** | ProTaper Gold® Sterile Files Assortment | **A0411221G0303** | ProTaper Gold® Sterile Finishing Files |
| **A0409225G0103** | ProTaper Gold® Sterile Files Assortment | **A0411221G0403** | ProTaper Gold® Sterile Finishing Files |
| **A0409225GD103** | ProTaper Gold® DEMO PACK / Sterile Files Assortment | **A0411221G0503** | ProTaper Gold® Sterile Finishing Files |
| **A0409231G0103** | ProTaper Gold® Sterile Files Assortment | **A0411225G0103** | ProTaper Gold® Sterile Finishing Files |
| **A0410219G0103** | ProTaper Gold® Sterile Shaping Files | **A0411225G0203** | ProTaper Gold® Sterile Finishing Files |
| **A0410221G0103** | ProTaper Gold® Sterile Shaping Files | **A0411225G0303** | ProTaper Gold® Sterile Finishing Files |
| **A0410221G0203** | ProTaper Gold® Sterile Shaping Files | **A0411225G0403** | ProTaper Gold® Sterile Finishing Files |
| **A0410225G0103** | ProTaper Gold® Sterile Shaping Files | **A0411225G0503** | ProTaper Gold® Sterile Finishing Files |
| **A0410225G0203** | ProTaper Gold® Sterile Shaping Files | **A0411231G0103** | ProTaper Gold® Sterile Finishing Files |
| **A0410231G0103** | ProTaper Gold® Sterile Shaping Files | **A0411231G0203** | ProTaper Gold® Sterile Finishing Files |
| **A0410231G0203** | ProTaper Gold® Sterile Shaping Files | **A0411231G0303** | ProTaper Gold® Sterile Finishing Files |
| **A0411221G0103** | ProTaper Gold® Sterile Finishing Files | **A0411231G0403** | ProTaper Gold® Sterile Finishing Files |
| **A0411221G0203** | ProTaper Gold® Sterile Finishing Files | **A0411231G0503** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04190SX** | ProTaper Gold® Sterile Shaping Files | **BSTPTG04250F4** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04210F1** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04250F5** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04210F2** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04250S1** | ProTaper Gold® Sterile Shaping Files |
| **BSTPTG04210F3** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04250S2** | ProTaper Gold® Sterile Shaping Files |
| **BSTPTG04210F4** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04310F1** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04210F5** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04310F2** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04210S1** | ProTaper Gold® Sterile Shaping Files | **BSTPTG04310F3** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04210S2** | ProTaper Gold® Sterile Shaping Files | **BSTPTG04310F4** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04250F1** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04310F5** | ProTaper Gold® Sterile Finishing Files |
| **BSTPTG04250F2** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04310S1** | ProTaper Gold® Sterile Shaping Files |
| **BSTPTG04250F3** | ProTaper Gold® Sterile Finishing Files | **BSTPTG04310S2** | ProTaper Gold® Sterile Shaping Files |
| **Classification and Rules (EU and UK)** | EU class: **IIa** following **Rule 6**<br>ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745<br>UK Class: **IIa** following **Rule 6**<br>ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002 | | |
| **Basic UDI-DI** | **++J00310031DQ** | | |
| **EMDN code / description** | **L159004 - ENDODONTIC RASPATORIES AND FILES** | | |
| **GMDN code / description** | **40529 - Rotary/reciprocating endodontic file/rasp, reusable** | | |
| **Intended purpose** | **Engine-driven 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.

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|---|---|
| **External references (Common Specifications, Standards, Regulations) applied** | See applicable LAS (List of Applicable Standards). |
| **EC Certificate** | EC certificate number: **MDR 741027**<br>Notified Body name: **BSI Group The Netherlands B.V.**<br>Notified Body address: **Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands**<br>Notified Body ID: **CE 2797**<br>Certificate expiration date: **16-08-2027** |
| **UK Certificate** | UK certificate number (valid to the date of issue): **Not yet issued.**<br>Notified Body name: **BSI Assurance UK Ltd**<br>Notified Body address: **Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom**<br>Notified Body ID: **UKCA 0086**<br>Certificate expiration date: **Not yet issued** |
| **Reference to the corresponding Technical Documentation** | Technical Documentation name: **Protaper Gold (RU, NiTi, Ro, MSA)**<br>Technical Documentation Index: **1000-TF_0_TDI_000030** |

Ballaigues, 06.12.2024

**Frédéric Mottier**
QA Director of Maillefer Instruments Holding Sàrl

## REVISION HISTORY

| REVISION LEVEL | PREPARED BY | DESCRIPTION OF CHANGE |
|---|---|---|
| 9 | A. Vialichka | First DoC under new MDR CE Certificate<br>8000 template according to the EU MDR used for the first time<br>Protaper Ultimate SKUs were moved to a dedicated DoC<br>*Note: Refer to the previous DoC for a complete revision history* |
| 10 | Franck Boutet | New template 8000-FM-008-05 [8].<br>CHANGE-PLN-2024-214: Addition of new SKU BSTPTG* (4 instruments variants). |

**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<br>I HENHOLD TIL BILAG VIII TIL FORORDNING 2017/745<br>GEMÄSS ANHANG VIII DER VERORDNUNG 2017/745<br>SASKAŅĀ AR REGULAS 2017/745 VIII PIELIKUMU<br>ZGODNIE Z ANEKSEM VIII DO ROZPORZĄDZENIA 2017/745<br>V SKLADU S PRILOGO VIII K UREDBI 2017/745<br>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<br>- 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)<br>ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.<br>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<br>- DU RÈGLEMENT UE/2017/745 RELATIF AUX DISPOSITIFS MÉDICAUX, CONFORMÉMENT À LA PROCÉDURE D'ÉVALUATION DE LA CONFORMITÉ.<br>TOUTES LES PIÈCES JUSTIFICATIVES SONT CONSERVÉES DANS LES LOCAUX DU FABRICANT.<br>LE FABRICANT EST EXCLUSIVEMENT RESPONSABLE DE LA DÉCLARATION DE CONFORMITÉ. |
| | VI ERKLÆRER HERMED PÅ EGET ANSVAR, AT OVENNÆVNTE PRODUKTER OPFYLDER BESTEMMELSERNE I<br>- FORORDNING EU/2017/745 OM MEDICINSK UDSTYR I OVERENSSTEMMELSE MED DEN OVERENSSTEMMELSESVURDERINGSPROCEDURE, DER ER BESKREVET.<br>AL UNDERSTØTTENDE DOKUMENTATION OPBEVARES HOS PRODUCENTEN.<br>PRODUCENTEN ER EKSKLUSIVT ANSVARLIG FOR OVERENSSTEMMELSESERKLÆRINGEN. |
| | WIR ERKLÄREN HIERMIT IN ALLEINIGER VERANTWORTUNG, DASS DIE OBEN GENANNTEN PRODUKTE DEN BESTIMMUNGEN DER<br>- VERORDNUNG EU/2017/745 ÜBER MEDIZINPRODUKTE ENTSPRECHEN, GEMÄSS DEN VERFAHREN ZUR KONFORMITÄTSBEWERTUNG.<br>ALLE UNTERSTÜTZENDEN DOKUMENTE WERDEN AM STANDORT DES HERSTELLERS AUFBEWAHRT.<br>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<br>- REGULĀ ES/2017/745, KAS ATTIECAS UZ MEDICĪNISKĀM IERĪCĒM, SASKAŅĀ AR ATBILSTĪBAS NOVĒRTĒŠANAS PROCEDŪRU.<br>VISA APLIECINOŠĀ DOKUMENTĀCIJA TIEK GLABĀTA RAŽOTĀJA TELPĀS.<br>PAR ATBILSTĪBAS DEKLARĀCIJU IR ATBILDĪGS TIKAI UN VIENĪGI RAŽOTĀJS. |

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| | NA NASZĄ WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ NINIEJSZYM ZAŚWIADCZAMY, ŻE WYŻEJ WYMIENIONE PRODUKTY SPEŁNIAJĄ WYMAGANIA OKREŚLONE W POSTANOWIENIACH<br>- ROZPORZĄDZENIA UE/2017/745 W SPRAWIE WYROBÓW MEDYCZNYCH ZGODNIE Z PROCEDURĄ OCENY ZGODNOŚCI.<br>CAŁOŚĆ POWIĄZANEJ DOKUMENTACJI JEST PRZECHOWYWANA PRZEZ PRODUCENTA.<br>WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ ZA DEKLARACJĘ ZGODNOŚCI PONOSI PRODUCENT. |
| | NA LASTNO ODGOVORNOST IZJAVLJAMO, DA ZGORAJ NAVEDENI IZDELKI IZPOLNJUJEJO DOLOČBE<br>- UREDBA EU/2017/745 O ZDRAVSTVENIH PRIPOMOČKIH, V SKLADU S POSTOPKOM OCENJEVANJA SODOBNOSTI.<br>VSO DOKAZNO DOKUMENTACIJO HRANI PROIZVAJALEC.<br>ZA IZJAVO O SKLADNOSTI JE ODGOVOREN IZKLJUČNO PROIZVAJALEC. |
| | YUKARIDA BELİRTİLEN ÜRÜNLERİN AB/2017/745 SAYILI TIBBİ CİHAZLAR YÖNETMELİĞİ HÜKÜMLERİNE UYGUN OLDUĞUNU,<br>- EKLERDE AÇIKLANAN UYGUNLUK DEĞERLENDİRME PROSEDÜRÜNE UYGUN OLARAK.<br>TÜM DESTEKLEYİCİ BELGELER ÜRETİCİNİN TESİSLERİNDE SAKLANMAKTADIR.<br>UYGUNLUK BEYANINDAN MÜNHASIRAN ÜRETİCİ SORUMLUDUR. |
| External references (Common Specifications, Standards, Regulations) applied | Références externes (Spécifications, Normes, Règlements communs) appliquées<br>Anvendte eksterne referencer (fælles specifikationer, standarder, forordninger)<br>Angewandte externe Referenzen (gemeinschaftliche Spezifikationen, Normen, Verordnungen)<br>Piemērotās ārējās atsauces (kopējās specifikācijas, standarti, noteikumi)<br>Zastosowane odniesienia zewnętrzne (wspólne specyfikacje, normy, rozporządzenia)<br>Uporaba zunanjih referenc (skupne specifikacije, standardi, predpisi)<br>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 |