

DoC - DECLARATION OF CONFORMITY



GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1000-TF_8_EUDOC_000179	REVISION LEVEL	7	PAGE NO	Page 1 of 5
------------------------	------------------------	-----------------------	---	----------------	-------------

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 Limited Address of the site: Brunel Way, Stonehouse, Gloucestershire, GL10 3GB, United Kingdom		
PRODUCT CODE / CATALOGUE NUMBER	NAME	PRODUCT CODE / CATALOGUE NUMBER	NAME
BDDW1GG125015	WaveOne® Gold Glider Endodontic Sterile Reciprocating Glide Path File	BSTW1GG621015	WaveOne® Gold Glider Endodontic Sterile Reciprocating Glide Path File
BSTW1GG321015	WaveOne® Gold Glider Endodontic Sterile Reciprocating Glide Path File	BSTW1GG625015	WaveOne® Gold Glider Endodontic Sterile Reciprocating Glide Path File
BSTW1GG325015	WaveOne® Gold Glider Endodontic Sterile Reciprocating Glide Path File	BSTW1GG631015	WaveOne® Gold Glider Endodontic Sterile Reciprocating Glide Path File
BSTW1GG331015	WaveOne® Gold Glider Endodontic Sterile Reciprocating Glide Path File	-	-
Classification and Rules (EU and UK)	EU class: Ila following Rule 6 ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: Ila following Rule 6 ACCORDING TO ANNEX IX OF THE EUROPEAN DIRECTIVE 93/42/EC AND UK MDR 2002		
Basic UDI-DI	++J00310040DR		
EMDN code / description	Q010507 / Endodontics Instrumentary single use (enlargers, file, rasps, etc)		
GMDN code / description	63550 / Rotary/reciprocating endodontic file/rasp, single-use		
Intended purpose	WaveOne Gold Glider are engine-driven instruments intended for root canal preparation (glide path)		
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF <ul style="list-style-type: none"> - 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 applicable LAS (List of Applicable Standards).		
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		
FORM NO	8000-FM-008-05	REVISION LEVEL	8

DoC - DECLARATION OF CONFORMITY**GROUP QUALITY SYSTEM – MULTI-USE FORM**

DOCUMENT NUMBER	1000-TF_8_EUDOC_000179	REVISION LEVEL	7	PAGE NO	Page 2 of 5
------------------------	------------------------	-----------------------	---	----------------	-------------

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: Not yet issued
Reference to the corresponding Technical Documentation	Technical Documentation name: WaveOne Gold Glider (SU, NiTi, Ro, MSA) Technical Documentation Index: 1000-TF_0_TDI_000066

Ballaigues, 06.01.2025

Frédéric Mottier
QA/Quality Compliance Director

FORM NO	8000-FM-008-05	REVISION LEVEL	8
----------------	----------------	-----------------------	---

DoC - DECLARATION OF CONFORMITY**GROUP QUALITY SYSTEM – MULTI-USE FORM**

DOCUMENT NUMBER	1000-TF_8_EUDOC_000179	REVISION LEVEL	7	PAGE NO	Page 3 of 5
------------------------	------------------------	-----------------------	---	----------------	-------------

REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
5	A. Vialichka	First DoC under new MDR CE Certificate 8000 template according to the EU MDR used for the first time <i>Note: Refer to the previous DoC for a complete revision history</i>
6	G. Pillet	Correcting document number mismatch
7	G. Pillet	Use of the new template 8000-FM-008-05 [8]. Change of UK-REP address (CHANGE-PLN-2024-561).

FORM NO	8000-FM-008-05	REVISION LEVEL	8
----------------	----------------	-----------------------	---

DoC - DECLARATION OF CONFORMITY



GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1000-TF_8_EUDOC_000179	REVISION LEVEL	7	PAGE NO	Page 4 of 6
------------------------	------------------------	-----------------------	---	----------------	-------------

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 / Pooblašteni 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.	<p>NOUS DÉCLARONS PAR LA PRÉSENTE, SOUS NOTRE SEULE RESPONSABILITÉ, QUE LES PRODUITS SUSMENTIONNÉS SATIFONT AUX DISPOSITIONS</p> <ul style="list-style-type: none"> - DU RÈGLEMENT UE/2017/745 RELATIF AUX DISPOSITIFS MÉDICAUX, CONFORMÉMENT À LA PROCÉDURE D'ÉVALUATION DE LA CONFORMITÉ. <p>TOUTES LES PIÈCES JUSTIFICATIVES SONT CONSERVÉES DANS LES LOCAUX DU FABRICANT. LE FABRICANT EST EXCLUSIVEMENT RESPONSABLE DE LA DÉCLARATION DE CONFORMITÉ.</p> <p>VI ERKLÆRER HERMED PÅ EGET ANSVAR, AT OVENNÆVNTE PRODUKTER OPFYLDER BESTEMMELSERNE I</p> <ul style="list-style-type: none"> - FORORDNING EU/2017/745 OM MEDICINSK Udstyr i OVERENSSTEMMELSE MED DEN OVERENSSTEMMELSESVURDERINGSPROCEDURE, DER ER BESKREVET. <p>AL UNDERSTØTTENDE DOKUMENTATION OPBEVARES HOS PRODUCENTEN. PRODUCENTEN ER EKSKLUSIVT ANSVARLIG FOR OVERENSSTEMMELSESERKLÆRINGEN.</p> <p>WIR ERKLÄREN HIERMIT IN ALLEINIGER VERANTWORTUNG, DASS DIE OBEN GENANNTEN PRODUKTE DEN BESTIMMUNGEN DER</p> <ul style="list-style-type: none"> - VERORDNUNG EU/2017/745 ÜBER MEDIZINPRODUKTE ENTSPRECHEN, GEMÄSS DEN VERFAHREN ZUR KONFORMITÄTBEWERTUNG. <p>ALLE UNTERSTÜTZENDEN DOKUMENTE WERDEN AM STANDORT DES HERSTELLERS AUFBEWAHRT.</p> <p>DIE VERANTWORTUNG FÜR DIE KONFORMITÄTSEKTLÄRUNG LIEGT AUSSCHLIESSLICH BEIM HERSTELLER</p> <p>MĒS AR ŠO VIENĪGI UZ SAVU ATBILDĪBU APLIECINĀM, KA IEPRIEKŠ MINĒTIE RAŽOJUMI ATBILST NOTEIKUMIEM, KAS PAREDZĒTI</p> <ul style="list-style-type: none"> - REGULĀ ES/2017/745, KAS ATTIECAS UZ MEDICĪNISKĀM IERĪCĒM, SASKAŅĀ AR ATBILSTĪBAS NOVĒRTĒŠANAS PROCEDŪRU. <p>VISA APLIECINOŠĀ DOKUMENTĀCIJA TIEK GLABĀTA RAŽOTĀJA Telpās.</p> <p>PAR ATBILSTĪBAS DEKLARĀCIJU IR ATBILDĪGS TIKAI UN VIENĪGI RAŽOTĀJS.</p>

FORM NO	8000-FM-008-05	REVISION LEVEL	8
----------------	----------------	-----------------------	---

GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1000-TF_8_EUDOC_000179	REVISION LEVEL	7	PAGE NO	Page 5 of 5
------------------------	------------------------	-----------------------	---	----------------	-------------

	<p>NA NASZĄ WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ NINIEJSZYM ZAŚWIADCZAMY, ŻE WYŻEJ WYMIENIONE PRODUKTY SPEŁNIAJĄ WYMAGANIA OKREŚLONE W POSTANOWIENIACH</p> <ul style="list-style-type: none"> - ROZPORZĄDZENIA UE/2017/745 W SPRAWIE WYROBÓW MEDYCZNYCH ZGODNIE Z PROCEDURĄ OCENY ZGODNOŚCI. <p>CAŁOŚĆ POWIĄZANEJ DOKUMENTACJI JEST PRZECHOWYWANA PRZEZ PRODUCENTA. WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ ZA DEKLARACJĘ ZGODNOŚCI PONOSI PRODUCENT.</p> <p>NA LASTNO ODGOVORNOST IZJAVLJAMO, DA ZGORAJ NAVEDENI IZDELKI IZPOLNJUJEJO DOLOČBE</p> <ul style="list-style-type: none"> - UREDBA EU/2017/745 O ZDRAVSTVENIH PRIPOMOČKIH, V SKLADU S POSTOPKOM OCENJEVANJA SODOBNOSTI. <p>VSO DOKAZNO DOKUMENTACIJO HRANI PROIZVAJALEC. ZA IZJAVO O SKLADNOSTI JE ODGOVOREN IZKLUČNO PROIZVAJALEC.</p> <p>YUKARIDA BELİRTİLEN ÜRÜNLERİN AB/2017/745 SAYILI TIBBİ CİHAZLAR YÖNETMELİĞİ HÜKÜMLERİNE UYGUN OLDUĞUNU,</p> <ul style="list-style-type: none"> - 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	<p>Références externes (Spécifications, Normes, Règlements communs) appliquées Anvendte eksterne referencer (fælles specifikationer, standarder, forordninger) Angewandte externe Referenzen (gemeinschaftliche Spezifikationen, Normen, Verordnungen) Piemērotās ārējās atsaucēs (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)</p>
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 priglašenege 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 priglašenege 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 priglašenege 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 / Henvising 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 dokumentation / Index der Technischen Dokumentation / Tehniskās dokumentācijas indekss / Nazwa dokumentacji technicznej / Indeks dokumentacji technicznej / Indeks tehnične dokumentacije / Teknik Dokümantasyon adı / Teknik Dokümantasyon Dizini