

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 670383****Issued To:**

**Maillefer Instruments Holding Sàrl
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland**

In respect of:

Design, development and manufacture of sterile and non-sterile dental instruments, motors and contra angles, dental reconstruction systems, dental devices for diagnosis, solutions for irrigation and cleaning of root canals, products for root canal obturation, sterile paperpoints. Those aspects of Annex II relating to securing and maintaining sterility in the manufacture of reamers and files and related to the accuracy of metrology of endodontic software with measuring function.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2017-05-24**

Date: **2021-02-19**

Expiry Date: **2023-07-08**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 670383**
Date: **2021-02-19**
Issued To: **Maillefer Instruments Holding Sàrl**
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland

Date	Reference Number	Action
24 May 2017	8707246	First issue. Transfer from another Notified Body.
06 July 2018	8923290	Certificate Renewal. Removal of 'non-sterile paperpoints' from scope.
19 February 2019	8963068	Traceable to NB 0086.
08 January 2020	3061958	Addition of subcontractors: M.D.T. Micro Diamond Technologies Ltd. ENICS Schweiz AG FORUM Engineering Technologies (96), Ltd. Dentsply Dental (Tianjin) Co., Ltd. Dentsply Indústria e Comércio Ltda Sor-Van Radiation Ltd. Removal of subcontractor: Maillefer Instruments Holding Sarl Le Creux
19 February 2021	3369178	eIFU Review completed (sampled eIFU "General Processing Instructions for Endodontic Products" (printed version) for ENDODONTIC FILES, BARBED BROACHES, PROBES, EXCAVATORS, PLUGGERS, SPREADERS, CONDENSORS, DRILLS, BURS, ULTASONIC TIPS, FILLING MATERIALS, PINS & POSTS, WORKING LENGTH TOOLS, OBTURATOR DIAMETER TOOLS) per the requirements of eIFU Regulation 207/2012.

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Page 1 of 2

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This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 670383**
Date: **2021-02-19**
Issued To: **Maillefer Instruments Holding Sàrl**
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland

Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
13 September 2021	3506075	Added EC REP 'Dentsply Detrey GmbH'
18 March 2024	3749757	Scope reduction following a voluntary withdrawals of product for commercial reasons. The following text was removed from the scope: "motors and contra angles", "dental devices for diagnosis", "and related to the accuracy of metrology of endodontic software with measuring function"

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

18 March 2024

Maillefer Instruments Holding Sàrl
Chemin du Verger 3
Ballaigues
CH-1338
Switzerland

To whom it may concern,

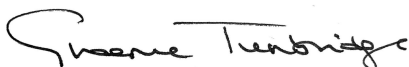
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 670383	93/42/EEC Annex II excluding Section 4	3749757	Scope reduction following a voluntary withdrawals of product for commercial reasons. The following text was removed from the scope: "motors and contra angles", "dental devices for diagnosis", "and related to the accuracy of metrology of endodontic software with measuring function"

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge
Senior Vice President, Medical Devices

DoC - DECLARATION OF CONFORMITY




CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1000-TF_8_EUDOC_000260	REVISION LEVEL	4	PAGE NO	Page 1 of 3
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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 ONY, United Kingdom	
PRODUCT CODE / CATALOGUE NUMBER	NAME	PRODUCT CODE / CATALOGUE NUMBER	NAME
A012X01800604	Readysteel® C+ Files For catheterization	A012X02101504	Readysteel® C+ Files For catheterization
A012X01800804	Readysteel® C+ Files For catheterization	A012X02102004	Readysteel® C+ Files For catheterization
A012X01801004	Readysteel® C+ Files For catheterization	A012X02190004	Readysteel® C+ Files For catheterization
A012X01801504	Readysteel® C+ Files For catheterization	A012X02500604	Readysteel® C+ Files For catheterization
A012X01802004	Readysteel® C+ Files For catheterization	A012X02500804	Readysteel® C+ Files For catheterization
A012X01890004	Readysteel® C+ Files For catheterization	A012X02501004	Readysteel® C+ Files For catheterization
A012X02100604	Readysteel® C+ Files For catheterization	A012X02501504	Readysteel® C+ Files For catheterization
A012X02100804	Readysteel® C+ Files For catheterization	A012X02502004	Readysteel® C+ Files For catheterization
A012X02101004	Readysteel® C+ Files For catheterization	A012X02590004	Readysteel® C+ Files For catheterization
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		++J00310001DF	
EMDN code		L159004 - ENDODONTIC RASPATORIES AND FILES	
GMDN Code / description		31878 - Manual endodontic file/rasp, reusable	
Intended purpose: Manual instrument intended for canal scouting, canal negotiation and glide path for further preparation with other instruments.			
WE HEREWITHTH 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	

FORM NO	8000-FM-008-05	REVISION LEVEL	3
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DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
DOCUMENT NUMBER	1000-TF_8_EUDOC_000260	REVISION LEVEL	4	PAGE NO	Page 2 of 3

	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: C+ file (RU, SST, Ma, MSA) Technical Documentation Index: 1000-TF_0_TDI_000020
Expiration date for the DoC	Covered by the validity date of EC certificate.

Ballaigues, 12.09.2022



Frédéric Mottier
QA/RC Director of Maillefer Instruments Holding Sàrl.

FORM NO	8000-FM-008-05	REVISION LEVEL	3
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DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

LEGAL MANUFACTURER**NAME, ADDRESS**

Name und Adresse des Herstellers

VDW GmbH

Bayerwaldstraße 15
81737 München / Munich
Deutschland / Germany**SINGLE REGISTRATION NUMBER (SRN)**

Registrierungsnummer des Herstellers

DIMDI Registration Number: DE/0000029227

AUTHORIZED REPRESENTATIVE NAME, ADDRESS

Name und Adresse des Repräsentanten

N/A

PRODUCT GROUP

Produktgruppe

Sterile root canal instruments for repeated use

PRODUCT NAME / MD NOMENCLATURE

Produktbezeichnung / MP Nomenklatur

Product Name	GMDN	UMDN
C-Pilot files	31878	16-662
Finger Plugger	41876	16-662
Finger Spreader	37678	16-662
Flexicut files	31878	16-662
Hedstroem files	31878	16-662
K-reamers	31878	16-662
K-files	31878	16-662
NiTi Finger Spreader	37678	16-662
NiTi K-files	31878	16-662
Stainless hand files for RECIPROC	31878	16-662
Hand files for VDW.ROTATE	31878	16-662

RISK CLASS

Risikoklasse

Class Is / Rule 6

CATALOG (SKU) NUMBER OR BASIC UDI-DI

Artikelnummer oder Basic UDI-DI

Please refer to PRODUCT LIST - ATTACHMENT

COMMON SPECIFICATION

Spezifikation

The technical documentation is available as paper version on file.

NOTIFIED BODY NAME

Name der Benannten Stelle

TÜV SÜD Product Service GmbH

Ridlerstr. 65
80339 München / Munich
CE 0123**NOTIFIED BODY IDENTIFICATION NUMBER**

Identifikation der Benannten Stelle

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

APPLICABLE EU LEGISLATIONS & CONFORMITY ASSESSMENT PROCEDURE

Konformitätsbewertungsverfahren

CERTIFICATE(S) ISSUED,
Ausstellung des Zertifikats

CERTIFICATE(S) VALIDITY DATE
Gültigkeitsdatum des Zertifikats

☒ **MDD 93/42/EWG, Amendment 2007/47/EEC.**
Annex V

☐ **MDR 2017/745**

Certificate No / Rev.: G2S 015409 0027 Rev. 00

26.05.2024

STATEMENT OF DECLARATION

STELLUNGNAHME DER ERKLÄRUNG

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER AND CONFORMS TO ALL APPLICABLE REGULATIONS AND COMMON SPECIFICATION.

NAME, TITLE, FUNCTION

Petra Altmann-Peichl, Director QA/RA

PLACE, DATE OF ISSUE

Munich, 20.05.2021

VALIDITY DATE

Please see: CERTIFICATE(S) VALIDITY DATE

REV. Nr.

30



BAYERWALDSTR. 15, 81737 MÜNCHEN
TEL. 089 / 6 27 34-0, FAX 089 / 6 27 34 - 304

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

PRODUCT LIST - ATTACHMENT:
CATALOG(SKU) NUMBER OR BASIC UDI-DI (Artikelnummer oder Basic UDI-DI)

C-Pilot files

V040368019006	V040368019008	V040368019010	V040368019012	V040368019015
V040368019210	V040368021006	V040368021008	V040368021010	V040368021012
V040368021015	V040368021210	V040368025006	V040368025008	V040368025010
V040368025012	V040368025015	V040368025210		

Finger Plugger

V040399025015	V040399025020	V040399025025	V040399025030	V040399025035
V040399025040	V040399025230			

Finger Spreader

V040395025015	V040395025020	V040395025025	V040395025030	V040395025035
V040395025040	V040395025230			

Flexicut files

V040364021015	V040364021020	V040364021025	V040364021030	V040364021035
V040364021040	V040364021230	V040364025015	V040364025020	V040364025025
V040364025030	V040364025035	V040364025040	V040364025230	

Hedstroem files

V040373021008	V040373021010	V040373021015	V040373021020	V040373021025
V040373021030	V040373021035	V040373021040	V040373021045	V040373021050
V040373021055	V040373021060	V040373021070	V040373021080	V040373021090
V040373021100	V040373021110	V040373021220	V040373021230	V040373021240
V040373021250	V040373025008	V040373025010	V040373025015	V040373025020
V040373025025	V040373025030	V040373025035	V040373025040	V040373025045
V040373025050	V040373025055	V040373025060	V040373025070	V040373025080
V040373025090	V040373025100	V040373025110	V040373025120	V040373025130
V040373025140	V040373025220	V040373025230	V040373025240	V040373025260
V040373028008	V040373028010	V040373028220	V040373031008	V040373031010
V040373031015	V040373031020	V040373031025	V040373031030	V040373031035
V040373031040	V040373031045	V040373031050	V040373031055	V040373031060
V040373031070	V040373031080	V040373031090	V040373031100	V040373031110
V040373031120	V040373031130	V040373031140	V040373031220	V040373031230
V040373031240	V040373031260			

K-reamers

V040353021006	V040353021008	V040353021010	V040353021015	V040353021020
V040353021025	V040353021030	V040353021035	V040353021040	V040353021045
V040353021050	V040353021055	V040353021060	V040353021070	V040353021080
V040353021090	V040353021100	V040353021110	V040353021210	V040353021230
V040353021240	V040353021250	V040353025006	V040353025008	V040353025010
V040353025015	V040353025020	V040353025025	V040353025030	V040353025035
V040353025040	V040353025045	V040353025050	V040353025055	V040353025060
V040353025070	V040353025080	V040353025090	V040353025100	V040353025110
V040353025120	V040353025130	V040353025140	V040353025210	V040353025230
V040353025240	V040353025260	V040353028006	V040353028008	V040353028010
V040353028210	V040353031006	V040353031008	V040353031010	V040353031015

DECLARATION OF CONFORMITY

KONFORMITÄTSERKLÄRUNG

V040353031020	V040353031025	V040353031030	V040353031035	V040353031040
V040353031045	V040353031050	V040353031055	V040353031060	V040353031070
V040353031080	V040353031090	V040353031100	V040353031110	V040353031120
V040353031130	V040353031140	V040353031210	V040353031230	V040353031240
V040353031260				

K-files

V040363021006	V040363021008	V040363021010	V040363021012	V040363021015
V040363021017	V040363021020	V040363021025	V040363021030	V040363021035
V040363021040	V040363021045	V040363021050	V040363021055	V040363021060
V040363021070	V040363021080	V040363021090	V040363021100	V040363021110
V040363021210	V040363021230	V040363021240	V040363021250	V040363025006
V040363025008	V040363025010	V040363025012	V040363025015	V040363025017
V040363025020	V040363025025	V040363025030	V040363025035	V040363025040
V040363025045	V040363025050	V040363025055	V040363025060	V040363025070
V040363025080	V040363025090	V040363025100	V040363025110	V040363025120
V040363025130	V040363025140	V040363025210	V040363025230	V040363025240
V040363025260	V040363028006	V040363028008	V040363028010	V040363028210
V040363031006	V040363031008	V040363031010	V040363031015	V040363031020
V040363031025	V040363031030	V040363031035	V040363031040	V040363031045
V040363031050	V040363031055	V040363031060	V040363031070	V040363031080
V040363031090	V040363031100	V040363031110	V040363031120	V040363031130
V040363031140	V040363031210	V040363031230	V040363031240	V040363031260

NiTi Finger Spreader

V040392025015	V040392025020	V040392025025	V040392025030	V040392025035
V040392025040	V040392025230			

NiTi K-files

V040362021015	V040362021020	V040362021025	V040362021030	V040362021035
V040362021040	V040362021045	V040362021050	V040362021055	V040362021060
V040362021230	V040362025015	V040362025020	V040362025025	V040362025030
V040362025035	V040362025040	V040362025045	V040362025050	V040362025055
V040362025060	V040362025230			

Stainless Files for RECIPROC

V040009025321

Hand files for VDW.ROTATE

V040009025322


DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1000-TF_8_EUDOC_000283	REVISION LEVEL	3	PAGE NO	Page 1 of 3
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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 ONY, United Kingdom	
PRODUCT CODE / CATALOGUE NUMBER	NAME	PRODUCT CODE / CATALOGUE NUMBER	NAME
A001522101303	PathFile® Glide Path File Sterile	A001522501903	PathFile® Glide Path File Sterile
A001522101603	PathFile® Glide Path File Sterile	A001522590003	PathFile® Glide Path File Sterile
A001522101903	PathFile® Glide Path File Sterile	A001523101303	PathFile® Glide Path File Sterile
A001522190003	PathFile® Glide Path File Sterile	A001523101603	PathFile® Glide Path File Sterile
A001522501303	PathFile® Glide Path File Sterile	A001523101903	PathFile® Glide Path File Sterile
A001522501603	PathFile® Glide Path File Sterile	A001523190003	PathFile® Glide Path File Sterile
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 DIRECTIVE 93/42/EC AND UK MDR 2002	
Basic UDI-DI		++J00310026DX	
EMDN code		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 (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.			
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: Pathfile (SU, NiTi, Ro, MSA) Technical Documentation Index: 1000-TF_0_TDI_000033	
Expiration date for the DoC		Covered by the validity date of EC certificate.	

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
DOCUMENT NUMBER	1000-TF_8_EUDOC_000283	REVISION LEVEL	3	PAGE NO	Page 2 of 3

Ballaigues, 12.09.2022



Frédéric Mottier
QA/RC Director of Maillefer Instruments Holding Sàrl.

FORM NO	8000-FM-008-05	REVISION LEVEL	3
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DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1000-TF_8_EUDOC_000173	REVISION LEVEL	9	PAGE NO	Page 1 of 3
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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
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
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 DIRECTIVE 93/42/EC AND UK MDR 2002		
Basic UDI-DI	++J00310031DQ		
EMDN code	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)			

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
DOCUMENT NUMBER	1000-TF_8_EUDOC_000173	REVISION LEVEL	9	PAGE NO	Page 2 of 3

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: Protaper Gold (RU, NiTi, Ro, MSA) Technical Documentation Index: 1000-TF_0_TDI_000030
Expiration date for the DoC	Covered by the validity date of EC certificate.

Ballaigues, 12.09.2022



Frédéric Mottier
QA/RC Director of Maillefer Instruments Holding Sàrl.

FORM NO	8000-FM-008-05	REVISION LEVEL	3
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DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1000-TF_8_EUDOC_000273	REVISION LEVEL	3	PAGE NO	Page 1 of 6
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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 ONY, United Kingdom	
PRODUCT CODE / CATALOGUE NUMBER	NAME	PRODUCT CODE / CATALOGUE NUMBER	NAME
A012C01801504	READYSTEEL® K-FLEXOFIL®	A012D02513004	READYSTEEL® K-FILE
A012C01802004	READYSTEEL® K-FLEXOFIL®	A012D02514004	READYSTEEL® K-FILE
A012C01802504	READYSTEEL® K-FLEXOFIL®	A012D02590004	READYSTEEL® K-FILE
A012C01803004	READYSTEEL® K-FLEXOFIL®	A012D02590104	READYSTEEL® K-FILE
A012C01803504	READYSTEEL® K-FLEXOFIL®	A012D02590204	READYSTEEL® K-FILE
A012C01804004	READYSTEEL® K-FLEXOFIL®	A012D02800604	READYSTEEL® K-FILE
A012C01890004	READYSTEEL® K-FLEXOFIL®	A012D02800804	READYSTEEL® K-FILE
A012C02100604	READYSTEEL® K-FLEXOFIL®	A012D02801004	READYSTEEL® K-FILE
A012C02100804	READYSTEEL® K-FLEXOFIL®	A012D02801504	READYSTEEL® K-FILE
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A012C02103004	READYSTEEL® K-FLEXOFIL®	A012D02804004	READYSTEEL® K-FILE
A012C02103504	READYSTEEL® K-FLEXOFIL®	A012D02804504	READYSTEEL® K-FILE
A012C02104004	READYSTEEL® K-FLEXOFIL®	A012D02805004	READYSTEEL® K-FILE
A012C02104504	READYSTEEL® K-FLEXOFIL®	A012D02805504	READYSTEEL® K-FILE
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CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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A012C02503004	READYSTEEL® K-FLEXOFIL®	A012D03104004	READYSTEEL® K-FILE
A012C02503504	READYSTEEL® K-FLEXOFIL®	A012D03104504	READYSTEEL® K-FILE
A012C02504004	READYSTEEL® K-FLEXOFIL®	A012D03105004	READYSTEEL® K-FILE
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A012C02505504	READYSTEEL® K-FLEXOFIL®	A012D03107004	READYSTEEL® K-FILE
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A012C02510004	READYSTEEL® K-FLEXOFIL®	A012D03112004	READYSTEEL® K-FILE
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A012C02590004	READYSTEEL® K-FLEXOFIL®	A012D03190204	READYSTEEL® K-FILE
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DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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A012C03114004	READYSTEEL® K-FLEXOFILE®	A101202100804	Readysteel® Senseus® FlexoFile®
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CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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A012D02190204	READYSTEEL® K-FILE	A101202508004	Readysteel® Senseus® FlexoFile®
A012D02500604	READYSTEEL® K-FILE	A101202590004	Readysteel® Senseus® FlexoFile®
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A012D02512004	READYSTEEL® K-FILE	A101203190104	Readysteel® Senseus® FlexoFile®
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		++J00310006DR	
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 HEREWITHTH 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	

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CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
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	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: K-Files (RU, SST, Ma, MSA) Technical Documentation Index: 1000-TF_0_TDI_000009
Expiration date for the DoC	Covered by the validity date of EC certificate.

Ballaigues, 12.09.2022



Frédéric Mottier
QA/RC Director of Maillefer Instruments Holding Sàrl.

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