

Document Detail

Type: 1000-TF_8_EUDOC
Document No.: 1000-TF_8_EUDOC_000217[05]
Title: GPP (JCM-Hantech, MSA)_EC Declaration of Conformity
Comment:
Status: CURRENT
Effective Date: 12-Oct-2023

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
1000- RC Specialist	Guillaume Pillet	10-Oct-2023 1:02 pm	GMT
ENDODONTICS RC Specialist			
1000- Site Quality Assurance Lead	Frederic Mottier	12-Oct-2023 6:45 am	GMT
ENDODONTICS Site Quality Assurance Lead			

DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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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
B00PGGPF000F1	ProTaper Gold® Conform Fit® Gutta Percha	B00TNGPF00AS4	TruNatomy® Conform Fit® Gutta Percha
B00PGGPF000F2	ProTaper Gold® Conform Fit® Gutta Percha	B00TNGPF00AST	TruNatomy® Conform Fit® Gutta Percha
B00PGGPF000F3	ProTaper Gold® Conform Fit® Gutta Percha	B00TNGPF00LRG	TruNatomy® Conform Fit® Gutta Percha
B00PGGPF00F23	ProTaper Gold® Conform Fit® Gutta Percha	B00TNGPF00MED	TruNatomy® Conform Fit® Gutta Percha
B00PGGPF00F45	ProTaper Gold® Conform Fit® Gutta Percha	B00TNGPF00PRM	TruNatomy® Conform Fit® Gutta Percha
B00PNGPF000X2	ProTaper Next® Conform Fit® Gutta Percha	B00TNGPF00SML	TruNatomy® Conform Fit® Gutta Percha
B00PNGPF000X3	ProTaper Next® Conform Fit® Gutta Percha	B00WGGPF00AST	WaveOne Gold® Conform Fit® Gutta Percha
B00PNGPF00X23	ProTaper Next® Conform Fit® Gutta Percha	B00WGGPF00LRG	WaveOne Gold® Conform Fit® Gutta Percha
B00PNGPF00X45	ProTaper Next® Conform Fit® Gutta Percha	B00WGGPF00MED	WaveOne Gold® Conform Fit® Gutta Percha
B00WGGPF00SML	WaveOne Gold® Conform Fit® Gutta Percha	B00WGGPF00PRI	WaveOne Gold® Conform Fit® Gutta Percha
Classification and Rules (EU and UK)		EU class: Ila following Rule 8 ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: Ila following Rule 8 ACCORDING TO ANNEX IX OF THE EUROPEAN DIRECTIVE 93/42/EC AND UK MDR 2002	
Basic UDI-DI:		++J00310043DX	
EMDN code / description:		Q01010203/ Dental Cones	
GMDN code / description:		45081 / Synthetic Gutta-Percha	
Intended purpose:		Device intended for filling of 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. - 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, Regulations) applied		See List of Applicable Standards (see Technical Documentation Index for document number).	

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CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
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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: GPP (JCM/Hantech, MSA) Technical Documentation Index: 1000-TF_0_TDI_000034

Ballaigues, 10.10.2023



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

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