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Comment:
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Effective Date: 16-Jun-2021

Approval

| <u>Owner Role</u> | <u>Sign-off By</u> | <u>Sign-off Date</u> | |
|--|--------------------|----------------------|-----|
| 1000- RC Specialist ENDODONTICS RC Specialist | Robert Meissner | 16-Jun-2021 4:44 pm | GMT |

EC Declaration of Conformity

DECLARATION OF CONFORMITY

LEGAL MANUFACTURER'S
NAME, ADDRESS

Mallefer Instruments Holding Sàrl

*Chemin du Verger 3
CH-1338 Ballaigues
Switzerland*

SINGLE REGISTRATION NUMBER
(SRN)

N/A

AUTHORIZED REPRESENTATIVE
NAME, ADDRESS

*DENTSPLY DeTrey GmbH
DeTrey Strasse 1
D-78467 Konstanz*

COMMON SPECIFICATIONS

N/A

NOTIFIED BODY'S NAME,
ADDRESS

*BSI The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands*

NOTIFIED BODY IDENTIFICATION
NUMBER

CE 2797

APPLICABLE EU LEGISLATIONS &
CONFORMITY ASSESSMENT
PROCEDURE

MDD 93/42/EEC, Amendment 2007/47/EEC.
Annex II – excluding Section 4

MDR 2017/745

Others:

CERTIFICATE(S) ISSUED

CE 670383

CERTIFICATE(S) VALIDITY DATE

08.07.2023

TECHNICAL DOCUMENTATION
DEMONSTRATING THE
CONFORMITY TO THE ABOVE
LEGISLATION'S REQUIREMENTS

1000-TF_0_TFDL_000070 (major version 0)

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STATEMENT OF DECLARATION

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

NAME, FUNCTION

Mottier Frédéric, QA/RC Director



PLACE, DATE OF ISSUE

Ballaigues, Switzerland, 11.06.2021

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PRODUCTS LIST

| CATALOG (SKU) NUMBER & BASIC UDI-DI (if applicable) | PRODUCT NAME / TRADE NAME | INTENDED PURPOSE | PRODUCT NOMENCLATURE CODE | DEVICE GROUP CODE | RISK CLASS |
|---|--|---|---|----------------------------|-------------------------------|
| B00PGGPF000F1 | ProTaper Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | CND: Q01010203 - DENTAL CONES GMDN: 31872 – Natural Gutta-Percha | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00PGGPF000F2 | ProTaper Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00PGGPF000F3 | ProTaper Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00PGGPF000F23 | ProTaper Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00PGGPF000F45 | ProTaper Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00PNGPF000X2 | ProTaper Next® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |

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|---------------|--|---|--|----------------------------|-------------------------------|
| B00PNGPF000X3 | ProTaper Next® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00PNGPF00X23 | ProTaper Next® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00PNGPF00X45 | ProTaper Next® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00TNGPF00AST | TruNatomy® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00TNGPF00MED | TruNatomy® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00TNGPF00PRM | TruNatomy® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00TNGPF00SML | TruNatomy® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |

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|---------------|---|---|--|----------------------------|-------------------------------|
| | | corresponding shaping file system | | | |
| B00WGGPF00AST | WaveOne Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00WGGPF00LRG | WaveOne Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00WGGPF00MED | WaveOne Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00WGGPF00PRI | WaveOne Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |
| B00WGGPF00SML | WaveOne Gold® Conform Fit™ Gutta Percha | Device intended for filling of the shaped, cleaned and irrigated root canal space prepared by the corresponding shaping file system | | MD 0402 / Dental materials | Class IIa (rule 8-1st Hyphen) |

Document History:

| Version | Date | Change Summary |
|---------|------------|--|
| 2 | 25.05.2021 | Major version number added to Technical Documentation List |

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| 3 | 11.06.2021 | <i>Addition of European representative - CHANGE-PLN-2021-42</i> |
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