

Document Detail

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Comment  
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Approvals

| Role                                   | Sign-off By   | Sign-off Date        |     |
|----------------------------------------|---------------|----------------------|-----|
| ENDODONTICS Product Compliance Manager | Thierry Utard | 12-Apr-2019 11:31 am | GMT |

# EU Declaration of Conformity

Rev.[4]

We,

**MAILLEFER INSTRUMENTS HOLDING Sàrl**

**Chemin du verger 3, CH-1338 Ballaigues / Switzerland**

declare on our own responsibility that all medical devices listed in **Annex I** conform to the requirements of the following directives:

- **Directive 93/42/EEC** concerning medical devices;

This declaration is based on the following data:

- Technical documentation demonstrating the product conformity to the requirements of the directive(s) mentioned above.
- Applied norms: **List of Applicable Standards of Technical File "PROTAPER GOLD"**.
- For class IIa products: The EC Certificate n° **CE 670383** of acceptance of the complete assurance system according to conformity assessment procedure: **Annex II excluding section 4 of Directive 93/42/EEC**.
- Notified body: **BSI Group The Netherlands B.V.** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

**MAILLEFER INSTRUMENTS HOLDING Sàrl** maintains a quality management system that complies with the **US FDA 21 CFR Part 820, EN ISO 13485:2016, Japanese PMDL law and TGA Medical Device Regulations**. All devices are designed, manufactured, tested and released for sale in accordance with related technical documentation.

09/04/2019

**MAILLEFER INSTRUMENTS HOLDING Sàrl**



**Luc ETIENNE**  
Management Representative

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Rev.[4]

## Annex I: Product list

| Product Ref.  | Product designation                          | Intended use                                                   | GMDN code & designation                     | MDD Classification | Rule | Sterile<br>Yes: S/<br>No: - |
|---------------|----------------------------------------------|----------------------------------------------------------------|---------------------------------------------|--------------------|------|-----------------------------|
| A0409221G0103 | PROTAPER<br>GOLD Sterile<br>Files Assortment | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0409225G0103 | PROTAPER<br>GOLD Sterile<br>Files Assortment | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0409231G0103 | PROTAPER<br>GOLD Sterile<br>Files Assortment | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0409225GD103 | PROTAPER<br>GOLD Sterile<br>Files Assortment | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0410219G0103 | PROTAPER<br>GOLD Sterile<br>Shaping Files    | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0410221G0103 | PROTAPER<br>GOLD Sterile<br>Shaping Files    | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0410221G0203 | PROTAPER<br>GOLD Sterile<br>Shaping Files    | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0410225G0103 | PROTAPER<br>GOLD Sterile<br>Shaping Files    | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |
| A0410225G0203 | PROTAPER<br>GOLD Sterile<br>Shaping Files    | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila                | 6    | S                           |

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|               |                                             |                                                                |                                             |     |   |   |
|---------------|---------------------------------------------|----------------------------------------------------------------|---------------------------------------------|-----|---|---|
| A0410231G0103 | PROTAPER<br>GOLD Sterile<br>Shaping Files   | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0410231G0203 | PROTAPER<br>GOLD Sterile<br>Shaping Files   | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411221G0103 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411221G0203 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411221G0303 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411221G0403 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411221G0503 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411225G0103 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411225G0203 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411225G0303 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411225G0403 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |

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|               |                                             |                                                                |                                             |     |   |   |
|---------------|---------------------------------------------|----------------------------------------------------------------|---------------------------------------------|-----|---|---|
| A0411225G0503 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411231G0103 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411231G0203 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411231G0303 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411231G0403 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |
| A0411231G0503 | PROTAPER<br>GOLD Sterile<br>Finishing Files | For cleaning and shaping<br>of the dental root canal<br>system | 40529 – Rotary endodontic<br>rasp, reusable | Ila | 6 | S |

## Document History:

| Version | Date       | Change Summary                                                                                                          |
|---------|------------|-------------------------------------------------------------------------------------------------------------------------|
| 02      | 31.05.2017 | Update of the previous DoC (1450-RDT_Dec of Conf_Protaper Gold) following to our Notified Body change (LNE GMED → BSI). |
| 03      | 26.07.2018 | Update of the product list.                                                                                             |
| 04      | 13.02.2019 | Update with the new template                                                                                            |
| 05      | 10.04.2019 | Update of Notified Body Name and Address (BSI UK → BSI NL).                                                             |