

*Document Detail*

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**Comment**  
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**Effective Date:** 22-Apr-2016

*Approvals*

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
			GMT

# EU Declaration of Conformity

## Class IIa products

We

**MAILLEFER INSTRUMENTS HOLDING Sàrl and its subsidiaries**

(including the subsidiaries: Maillefer Instruments Trading Sàrl, Maillefer Instruments Manufacturing Sàrl,  
Maillefer Instruments Consulting Sàrl)  
Trading as Dentsply Maillefer

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

declare on our own responsibility that all medical devices listed in **Annex I** are 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: **Listed in Technical File "PROTAPER GOLD"**.
- The EC Certificate n°**10468** of acceptance of the complete assurance system according to conformity assessment procedure: **Annex II excluding section 4 of the Directive 93/42/EEC**
- Notified body: **LNE/G-MED, 1 rue Gaston Boissier, 75724 Paris Cedex 15, France.**

Dentsply Maillefer's Division maintains a quality management system that complies with the United States Food and Drug Administration **21 CFR Part 820, EN ISO 13485:2012, Japanese PMDL law**. All devices are designed, manufactured, tested and released for sale in accordance with related technical documentation.

Ballaigues, **24.03.2016**

**MAILLEFER INSTRUMENTS  
HOLDING Sàrl**



**Luc Etienne**  
Management Representative



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## Document History:

Versio n	Date	Change summary
01	24.03.2016	Creation of a specific Technical File for PROTAPER GOLD

## Annex I: Products list

Code	Reference	Product name	Intended use	GMDN	GMDN definition	Rul e	Class	S/M	Standards
N	A0409221G0103	PROTAPER GOLD Sterile Files Assortment	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S	See Technical File "PROTAPER GOLD" F 711.124 Description
N	A0409225G0103	PROTAPER GOLD Sterile Files Assortment	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S	
N	A0409225GD103	PROTAPER GOLD DEMO PACK/Sterile Files Assortment	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S	
N	A0409231G0103	PROTAPER GOLD Sterile Files Assortment	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S	
N	A0410219G0103	PROTAPER GOLD Sterile Shaping Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S	

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N	A0410221G0103	PROTAPER GOLD Sterile Shaping Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0410221G0203	PROTAPER GOLD Sterile Shaping Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0410225G0103	PROTAPER GOLD Sterile Shaping Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0410225G0203	PROTAPER GOLD Sterile Shaping Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0410231G0103	PROTAPER GOLD Sterile Shaping Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0410231G0203	PROTAPER GOLD Sterile Shaping Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411221G0103	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S

See Technical File  
"PROTAPER GOLD"  
F 711.124 Description



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N	A0411221G0203	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411221G0303	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411221G0403	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411221G0503	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411225G0103	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411225G0203	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411225G0303	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S

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N	A0411225G0403	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411225G0503	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411231G0103	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411231G0203	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
N	A0411231G0303	PROTAPER GOLD Sterile Finishing Files	For cleaning and shaping of the dental root canal system	40529	Rasp, endodontic, powered : for mechanized instruments	6	Ila	S
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Code designations:

-	Current
N	New
M	Modified
D	Discontinued
C	Cancelled