

## EC Declaration of Conformity

Rev.[8]

### DECLARATION OF CONFORMITY

LEGAL MANUFACTURER'S  
NAME, ADDRESS

Dentsply Tulsa Dental Specialties  
608 Rolling Hills Drive  
Johnson City, TN 37604 USA

SINGLE REGISTRATION NUMBER  
(SRN)

Not Applicable

AUTHORIZED REPRESENTATIVE  
NAME, ADDRESS

DENTSPLY DeTrey GmbH  
DeTrey Strasse 1  
D-78467 Konstanz  
Germany

COMMON SPECIFICATIONS

Not Applicable

NOTIFIED BODY'S NAME,  
ADDRESS

BSI Group 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.  
Example: Annex II – excluding Section 4

☐ MDR 2017/745

☐ Others:

CERTIFICATE(S) ISSUED

Certificate No: CE 514069

CERTIFICATE(S) VALIDITY DATE

26-05-2024

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

1000-TF\_0\_TDI\_000022 (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



Luiz Paulo Ribeiro  
Senior Design QA Manager

PLACE, DATE OF ISSUE

Johnson City Tennessee USA July 22, 2025

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## PRODUCTS LIST

| CATALOG (SKU)<br>NUMBER & BASIC UDI-<br>DI (if applicable) | PRODUCT NAME / TRADE<br>NAME          | INTENDED<br>PURPOSE                                                                      | PRODUCT<br>NOMENCLATURE CODE                    | DEVICE GROUP CODE            | RISK CLASS       |
|------------------------------------------------------------|---------------------------------------|------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------------|------------------|
| A241W00000103                                              | ProTaper Gold Paper Points            | Absorbent paper points are used for drying the root canal(s) during endodontic treatment | <u>CND:</u> Q01010401<br><br><u>GMDN:</u> 38777 | MD0402 /<br>Dental Materials | Class IIa/Rule 6 |
| A241W00000203                                              | ProTaper Gold Paper Points            |                                                                                          |                                                 |                              |                  |
| A241W00000303                                              | ProTaper Gold Paper Points            |                                                                                          |                                                 |                              |                  |
| A241W00000403                                              | ProTaper Gold Paper Points            |                                                                                          |                                                 |                              |                  |
| A241W00000503                                              | ProTaper Gold Paper Points            |                                                                                          |                                                 |                              |                  |
| A241W000090103                                             | ProTaper Gold Paper Points            |                                                                                          |                                                 |                              |                  |
| A175W00000L03                                              | WaveOne Gold Paper Points             |                                                                                          |                                                 |                              |                  |
| A175W00000M03                                              | WaveOne Gold Paper Points             |                                                                                          |                                                 |                              |                  |
| A175W00000P03                                              | WaveOne Gold Paper Points             |                                                                                          |                                                 |                              |                  |
| A175W00000S03                                              | WaveOne Gold Paper Points             |                                                                                          |                                                 |                              |                  |
| A175W0000AST03                                             | WaveOne Gold Paper Points             |                                                                                          |                                                 |                              |                  |
| BSTPULPMPP0F1                                              | ProTaper Ultimate Absorbent Points F1 |                                                                                          |                                                 |                              |                  |
| BSTPULPMPP0F2                                              | ProTaper Ultimate Absorbent Points F2 |                                                                                          |                                                 |                              |                  |

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|               |                                             |                                                                                                         |                                                 |                              |                  |
|---------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------------|------------------|
| BSTPULPMPP0F3 | ProTaper Ultimate<br>Absorbent Points F3    | Absorbent paper<br>points are used for<br>drying the root<br>canal(s) during<br>endodontic<br>treatment | <b>CND:</b> Q01010401<br><br><b>GMDN:</b> 38777 | MD0402 /<br>Dental Materials | Class IIa/Rule 6 |
| BSTPULPMPP0FX | ProTaper Ultimate<br>Absorbent Points FX    |                                                                                                         |                                                 |                              |                  |
| BSTPULPMPPFXL | ProTaper Ultimate<br>Absorbent Points FXL   |                                                                                                         |                                                 |                              |                  |
| BSTPULPMPPAST | ProTaper Ultimate<br>Absorbent Points F1-F3 |                                                                                                         |                                                 |                              |                  |

### Document History:

| Version | Date           | Change Summary                                                                                                                                                                                |
|---------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 00      | 12 August 2021 | Creation in New Template – Updated with Ultimate part numbers – DoC originally signed 24 May 2021                                                                                             |
|         |                | Creation in New Template – Updated with WaveOne Gold Assortment A175W000AST03. Approved as a non-significant change by BSI by Toufik Zakaria on 22 April 2025. BSI reference number T0084879. |