

Annex VII EC Declaration of Conformity

Manufacturer Name and Address: Kerr Corporation also trading as Pentron Clinical
1717 West Collins Avenue
Orange, California 92867 USA

Authorized Representative Name and Address: Kerr Italia
S.r.l., Via Passanti, 174
84018 Scafati, (SA), Italy

Technical File Name/Number: Traverse Endodontic Rotary Files
Endo-012

Product Tradename(s): Traverse™ Orifice Opener Files, Traverse™ Glide Path Files & Traverse™ Files

Device Identification: see Attachment 1

Classification and Rule(s): Class IIa, Rule 6

Notified Body: BSI Group The Netherlands B.V.

Notified Body Number: 2797

Conformity Assessment Procedure & Certificate Issued: Annex V
CE Certificate 00847

Declaration Statement:

We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

24 May 2021

Issue date



Name: Mark Dzendzel

Title: Director, Quality Assurance Systems



| Traverse Files - Attachment 1 to Annex VII EC Declaration of Conformity | |
|---|---|
| REF | Description |
| 818-8256 | Traverse Orifice Opener - .08/.25/17mm - R |
| 818-2146 | Traverse Orifice and Glide Path File - .06/.13/21mm - R |
| 818-2147 | Traverse Orifice and Glide Path File - .06/.13/25mm - R |
| 818-2148 | Traverse Orifice and Glide Path File - .06/.13/31mm - R |
| 818-2196 | Traverse Orifice and Glide Path File - .06/.18/21mm - R |
| 818-2197 | Traverse Orifice and Glide Path File - .06/.18/25mm - R |
| 818-2198 | Traverse Orifice and Glide Path File - .06/.18/31mm - R |
| 818-2156 | Traverse Rotary Glide Path File - .06/.13/21mm - R |
| 818-2157 | Traverse Rotary Glide Path File - .06/.13/25mm - R |
| 818-2158 | Traverse Rotary Glide Path File - .06/.13/31mm - R |
| 818-2186 | Traverse Rotary Glide Path File - .06/.18/21mm - R |
| 818-2187 | Traverse Rotary Glide Path File - .06/.18/25mm - R |
| 818-2188 | Traverse Rotary Glide Path File - .06/.18/31mm - R |