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:	Endodontic Root Canal Sealers Endo-010
Product Tradename(s):	Tubli-Seal, Tubli-Seal EWT, Tubli-Seal Xpress & Tubli-Seal EWT Xpress
Device Identification:	see Attachment 1
Classification and Rule(s):	Class IIa, Rule 8
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:

28 July 2021
Issue date

Name: Mark Dzendzel

Title: Director, Quality Assurance Systems

Tubli-Seal, Tubli-Seal EWT, Tubli-Seal Xpress & Tubli-Seal EWT Xpress - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	**Description**
00340	Tubli-Seal Standard Package
01081	Tubli-Seal Bulk Package
25903	Tubli-Seal EWT Standard Package
33640	Tubli-Seal Xpress
33641	Tubli-Seal EWT Xpress

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