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):	Sealapex & Sealapex 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

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Sealapex & Sealapex Xpress - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	**Description**
18432	Sealapex
18598	Sealapex Bulk Pack
33639	Sealapex Xpress

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