Kerr

Annex IV EC Declaration of Conformity

Manufacturer Name and Address:	Kerr Corporation also trading as Pentrol 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
Single Registration Number (SRN):	Not available
Technical File Name/Number:	Prophylaxis Pastes without Fluoride/ R112
Basic UDI-DI:	See Attachment 1
Product Tradename(s):	CleanPolish™, SuperPolish™, Cleanic™
Device Identification:	See Attachment 1
Classification and Rule(s):	Class I, Rule 5
Common Standards:	Not available
Notified Body:	Not applicable
Notified Body Number:	Not applicable
Conformity Assessment Procedure & Certificate issued:	Annex IV of MDR 2017/745 CE Certificate: N/A

Declaration Statement:

This declaration of conformity is issued under the sole responsibility of Kerr Corporation.

We hereby declare that the above-mentioned device(s) comply with EU MDR 2017/745.

Regulatory Affairs Signature:

Place and Issue date:
Orange, CA USA 17 August 2021

Name: Mark Dzendzel
Title: Director Quality Assurance Systems

Technical File # R112 Attachment 1 to Annex IV EC Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
3183	Cleanic in Tube without Fluoride	084139611000086AE
360	Cleanpolish	
361	Superpolish	
3210	Cleanic Refill Cartridge, without Fluoride	
3230	Cleanic Jar without Fluoride, 100 G	
3500	Hawe Implant Paste	
3151	Cleanic Prophy-Clip	084139611000087AG