Annex IV EC Declaration of Conformity

Manufacturer Name and Address:	KerrHawe SA Via Strecce 4, 6934 Bioggio, Switzerland
Authorized Representative Name and Address:	Kerr Italia S.r.l. Via Passanti, 332, 84018 Scafati (SA) Italy
Single Registration Number (SRN):	Not available
Technical File Name/Number:	KBI-IDN19002-TF – Rev 01
Basic UDI-DI:	See Attachment 1
Product Tradename(s):	Prophylaxis Pastes without Fluoride
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 IX of MDR 2017/745

Declaration Statement:

This declaration of conformity is issued under the sole responsibility of KerrHawe SA.

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

Regulatory Affairs Signature:

Place and Issue date:

Bioggio, 29 September 2020

Name: Galileo Bertolasi

Title: QA/RA Director – Kerr Europe

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Kerr

KBI-IDN19009-TF - Attachment 1 to Annex IV EC Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
3183	Cleanic in Tube without Fluoride	76110481000008GF
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	76110481000012G6

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