Kerr™

Annex V EC Declaration of Conformity

Manufacturer Name and Address:	Kerr Corporation 1717 W. Collins Ave., Orange, CA 92867, USA
Authorized Representative Name and Address:	Kerr Italia S.r.l. Via Passanti, 174 Scafati (SA) 84018, Italy
Technical File Name/Number:	Premise Flowable Technical File, R094
Product Tradename(s):	Premise Flowable
Device Identification:	See Attachment 1
Classification and Rule(s):	IIa per Annex IX, Rule 8
Notified Body:	BSI Group The Netherlands B.V.
Notified Body Number:	2797
Conformity Assessment Procedure & Certificate Issued:	Annex V – Production Quality Assurance CE Certificate Number 00847

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

Regulatory Affairs Signature:

22 October 2021
Issue date

Name: Mark Dzendzel
Title: Director, Quality Assurance Systems

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Premise Flowable – Attachment 1
to Annex V EC Declaration of Conformity

REF	Description
33371	Premise Flowable Assorted Kit
33372	PremIse Flowable 4 PK Syringes, A1
33373	Premise Flowable 4 PK Syirnges, A2
33374	Premise Flowable 4 PK Syirnges, A3
33375	Premise Flowable 4 PK Syirnges, A3.5
33376	Premise Flowable 4 PK Syirnges, B1
33385	Premise Flowable 4 PK Syirnges, B2
33377	Premise Flowable 4 PK Syirnges, C2
33378	Premise Flowable 4 PK Syirnges, Universal Opaque
33379	Premise Flowable 4 PK Syirnges, XL1
33380	Premise Flowable 4 PK Syirnges, XL2
33721	Premise Flowable Syringe, A1
33722	Premise Flowable Syringe, A2
33723	Premise Flowable Syringe, A3
33724	Premise Flowable Syringe, A3.5
33725	Premise Flowable Syringe, B1
33726	Premise Flowable Syringe, B2
33727	Premise Flowable Syringe, C2
33728	Premise Flowable Syringe, Universal Opaque
33729	Premise Flowable Syringe, XL1
33730	Premise Flowable Syringe, XL2