



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: Harmonize/SimpliShade/OptiShade Technical File, R011

Product Tradename(s): Harmonize

Device Identification: See Attachment 1

Classification and Rule(s): Ila 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:

21 September 2021

Issue date

Name: Mark Dzendzel

Title: Director, Quality Assurance Systems



**Harmonize – Attachment 1
to Annex V EC Declaration of Conformity**

REF	Description
36536	Harmonize A2 Dentine Syringe Refill
36546	Harmonize A3 Dentine Syringe Refill
36548	Harmonize A4 Dentine Syringe Refill
36537	Harmonize A2 Enamel Syringe Refill
36553	Harmonize A3 Enamel Syringe Refill
36538	Harmonize Translucent Amber Incisal Syringe Refill
36569	Harmonize Translucent Clear Incisal Syringe Refill
36570	Harmonize Translucent Grey Incisal Syringe Refill
36545	Harmonize A1 Dentine Syringe Refill
36547	Harmonize A3.5 Dentine Syringe Refill
36549	Harmonize B3 Dentine Syringe Refill
36550	Harmonize C4 Dentine Syringe Refill
36551	Harmonize XL2 Dentine Syringe Refill
36552	Harmonize A1 Enamel Syringe Refill
36554	Harmonize A3.5 Enamel Syringe Refill
36555	Harmonize A4 Enamel Syringe Refill
36556	Harmonize B1 Enamel Syringe Refill
36557	Harmonize B2 Enamel Syringe Refill
36558	Harmonize B3 Enamel Syringe Refill
36559	Harmonize B4 Enamel Syringe Refill
36560	Harmonize C1 Enamel Syringe Refill
36561	Harmonize C2 Enamel Syringe Refill
36562	Harmonize C3 Enamel Syringe Refill
36563	Harmonize C4 Enamel Syringe Refill
36564	Harmonize D2 Enamel Syringe Refill
36565	Harmonize D3 Enamel Syringe Refill
36566	Harmonize D4 Enamel Syringe Refill
36567	Harmonize XL Enamel Syringe Refill
36568	Harmonize Translucent Blue Incisal Syringe Refill
36539	Harmonize Translucent SuperClear Incisal Syringe Refill
36571	Harmonize A1 Dentine Unidose Refill
36572	Harmonize A2 Dentine Unidose Refill
36573	Harmonize A3 Dentine Unidose Refill
36574	Harmonize A3.5 Dentine Unidose Refill
36575	Harmonize A4 Dentine Unidose Refill
36576	Harmonize B3 Dentine Unidose Refill
36577	Harmonize C4 Dentine Unidose Refill
36578	Harmonize XL2 Dentine Unidose Refill
36579	Harmonize A1 Enamel Unidose Refill
36542	Harmonize A2 Enamel Unidose Refill



REF	Description
36581	Harmonize A3 Enamel Unidose Refill
36582	Harmonize A3.5 Enamel Unidose Refill
36583	Harmonize A4 Enamel Unidose Refill
36584	Harmonize B1 Enamel Unidose Refill
36585	Harmonize B2 Enamel Unidose Refill
36586	Harmonize B3 Enamel Unidose Refill
36587	Harmonize B4 Enamel Unidose Refill
36588	Harmonize C1 Enamel Unidose Refill
36589	Harmonize C2 Enamel Unidose Refill
36590	Harmonize C3 Enamel Unidose Refill
36591	Harmonize C4 Enamel Unidose Refill
36592	Harmonize D2 Enamel Unidose Refill
36593	Harmonize D3 Enamel Unidose Refill
36594	Harmonize D4 Enamel Unidose Refill
36595	Harmonize XL Enamel Unidose Refill
36543	Harmonize Translucent Amber Incisal Unidose Refill
36597	Harmonize Translucent Blue Incisal Unidose Refill
36598	Harmonize Translucent Clear Incisal Unidose Refill
36599	Harmonize Translucent Grey Incisal Unidose Refill
36638	Harmonize Sample Syringe Pack
36653	Harmonize Sample Unidose Pack A2E and A3E
36633	Harmonize Intro Kit Syringe
36634	Harmonize Intro Kit Unidose
36635	Harmonize Advanced Kit Syringe