

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, 332
84018 Scafati (SA), Italy

Technical File Name/Number: Harmonize/SimpliShade/OptiShade Technical File, R011

Product Tradename(s): SimpliShade, OptiShade

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:

30 SEPTEMBER 2020

Issue date



Name: Mark Dzendzel
Title: Director, Quality Assurance Systems



**SimpliShade/OptiShade – Attachment 1
to Annex V EC Declaration of Conformity**

REF	Description
37001	SimpliShade Syringe, Light
37002	SimpliShade Syringe, Medium
37003	SimpliShade Syringe, Dark
37005	SimpliShade Syringe, Universal Opaque
37006	SimpliShade Unidose 20 Pack, Light
37007	SimpliShade Unidose 20 Pack, Medium
37008	SimpliShade Unidose 10 Pack, Dark
37010	SimpliShade Unidose 10 Pack, Universal Opaque
37011	SimpliShade Sample Syringe, Light
37012	SimpliShade Sample Syringe, Medium
37013	SimpliShade Sample Unidose 5 Pack (2 Light, 2 Medium, 1 Dark)
36971	SimpliShade Syringe, Light
36972	SimpliShade Syringe, Medium
36973	SimpliShade Syringe, Dark
36975	SimpliShade Syringe, Universal Opaque
36976	SimpliShade Unidose 20 Pack, Light
36977	SimpliShade Unidose 20 Pack, Medium
36978	SimpliShade Unidose 10 Pack, Dark
36980	SimpliShade Unidose 10 Pack, Universal Opaque
36981	SimpliShade Sample Syringe, Light
36982	SimpliShade Sample Syringe, Medium
36983	SimpliShade Sample Unidose 5 Pack (2 Light, 2 Medium, 1 Dark)
37111	OptiShade Syringe, Light
37112	OptiShade Syringe, Medium
37113	OptiShade Syringe, Dark
37115	OptiShade Syringe, Universal Opaque
37116	OptiShade Unidose 20 Pack, Light
37117	OptiShade Unidose 20 Pack, Medium
37118	OptiShade Unidose 10 Pack, Dark
37120	OptiShade Unidose 10 Pack, Universal Opaque
37121	OptiShade Sample Syringe, Light
37122	OptiShade Sample Syringe, Medium
37123	OptiShade Sample Unidose 5 Pack (2 Light, 2 Medium, 1 Dark)