

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: Herculite XRV Ultra/SimpliShade BW/OptiShade BW Technical File, R092

Product Tradename(s): SimpliShade, OptiShade

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:

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
37004	SimpliShade Syringe, Bleach White
37009	SimpliShade Unidose 10 Pack, Bleach White
36974	SimpliShade Syringe, Bleach White
36979	SimpliShade Unidose 10 Pack, Bleach White
37114	OptiShade Syringe, Bleach White
37119	OptiShade Unidose 10 Pack, Bleach White