

## **Annex V EC Declaration of Conformity**

Manufacturer Name and Kerr Corporation

Address: 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:** OptiBond eXTRa Universal Technical File, R008

**Product Tradename(s):** OptiBond eXTRa Universal

**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** Annex V – Production Quality Assurance

**Procedure & Certificate Issued:** 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 2021

Issue date

Name: Mark Dzendzel

Title: Director, Quality Assurance Systems



## OptiBond eXTRa Universal – Attachment 1 to Annex V EC Declaration of Conformity

REF	Description
36658	OptiBond eXTRa Universal Bottle Kit
36659	OptiBond eXTRa Universal Unidose Kit
36660	OptiBond eXTRa Universal Bottle Primer Refill
36661	OptiBond eXTRa Universal Bottle Adhesive Refill
36662	OptiBond eXTRa Universal Unidose Sample
36663	OptiBond eXTRa Universal Bottle Kit Sample
36663M	OptiBond eXTRa Universal Marketing Study Sample