

## **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 |

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