



EC Declaration of Conformity

Manufacturer Name: Kerr Corporation
Business Address: 1717 West Collins Avenue
Orange, California 92867 USA

Device Category: Dental Adhesives

Classification: IIa per Annex IX, Rule 5

Technical File: OptiBond FL

GMDN Code and Term: 34782 Dental bonding agent, polymer based

Product Tradename(s): OptiBond FL

CE Authorized Representative: Kerr Italia s.r.l.
Via Passanti 332, I-84018 Scafati (SA) Italy

Harmonized Standards Applied: EN ISO 13485, EN ISO 14971, EN ISO 15223-1, EN 1041, EN 1641, EN ISO 10993-1, EN ISO 10993-3, EN ISO 10993-5, EN ISO 10993-6, EN ISO 10993-11, EN ISO 10993-12

Other Standards Applied: IEC 62366-1, ISO 10993-2, ISO 10993-10, ISO 29022, ISO 7405, ISO 8601, ASTM D4169

Declaration Statement:

We hereby declare that the product line(s) listed above and part numbers detailed in the attached Product List conform to the relevant provisions of the CE Council Directive 93/42/EEC dated 14 June 1993 as amended by 2007/47/EC in accordance with Annex V, section 3.2 Conformity Assessment Procedure as demonstrated by the CE Certificate No 00847, issued by BSI (British Standard Institution), Notified Body No 2797.

Regulatory Affairs Signature:

May 7, 2019
Issue date

Name: Jennifer Evans
Title: Sr. Director Regulatory Affairs



Product List	
REF	Description
35369	OptiBond FL Kit
35265	OptiBond FL Prime - Refill
35266	OptiBond FL Adhesive - Refill
33352	OptiBond FL Unidose, 50 Pack
33352E	OptiBond FL Unidose, 50 pack – International
26684	OptiBond FL Kit - International
25881	OptiBond FL Prime Refill – International
25882	OptiBond FL Adhesive Refill - International