



EC Declaration of Conformity

Manufacturer Name: Kerr Italia S.R.L.
Business Address: Via Passanti 332, I-84018 Scafati, (SA) Italy

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

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 01220, issued by BSI (British Standard Institution), Notified Body No 2797.

Signature:

27 May 2019

Issue date.

Name: Annabella Del Pozzo
Title: QS&EHS Manager



Product List	
REF	Description
26684E	OptiBond FL Kit
25881E	OptiBond FL Primer Refill
25882E	OptiBond FL Adhesive Refill