Kerr™

Annex IV EU Declaration of Conformity

Manufacturer Name and Address:	Kerr Italia S.r.l. Via Passanti, 174 Scafati (SA) 84018, Italy
Authorized Representative Name and Address:	N/A
Single Registration Number (SRN):	IT-MF-000007768
Technical File Name/Number:	OptiBond FL Technical File #R001
Basic UDI-DI:	See Attachment 1
Product Tradename(s):	See Attachment 1
Device Identification:	See Attachment 1
Classification and Rule(s):	Class IIa, Rule 8 (per Annex VIII)
Intended Purpose:	OptiBond FL is an adhesive resin used to bond the tooth to resin composite restorative materials. It is also used to bond core build-ups.
Notified Body:	BSI Group The Netherlands B.V.
Notified Body Number:	2797
Conformity Assessment Procedure & Certificate issued:	Annex XI Part A – Production Quality Assurance EU Quality Assurance Certificate: MDR 783335
Applicable Standards:	See Attachment 2

Declaration Statement:
This declaration of conformity is issued under the sole responsibility of Kerr Italia S.r.l. We hereby declare that the above-mentioned device(s) comply with EU MDR 2017/745.

Signed for and on behalf of Manufacturer: *Kerr Italia S.r.l*

Brea, CA USA	28-Jan-2025 | 00:46 CET	DocuSigned by: Jennifer Evans 8DF30BF54362465...
Place	Date of Issue	Name: Jennifer Evans Title: VP RA/QA Kerr Italia S.r.l.

OptiBond FL– Technical File # R001 Attachment 1 to Annex IV EU Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
33352E	OptiBond FL Unidose, 50 Pack	805151187100002252
25881E	OptiBond FL Primer Refill	805151187100002252
25882E	OptiBond FL Adhesive Refill	805151187100002252
26684 E	OptiBond FL Bottle Kit	805151187100002252

OptiBond FL – Applicable Standards Attachment 2 to Annex IV EU Declaration of Conformity	
Standard	**Title**
EN1641:2009	Dentistry - Medical devices for dentistry - Materials
EN ISO 13485:2016 EN ISO 13485/A11:2021 (ISO 13485:2016)	Medical Devices – Quality management systems
ISO 20417:2021 EN 20417:2021	Medical Devices - Information to be supplied by the manufacturer
ISO 8601-1:2019 ISO 8601-1:2019+A1:2022	Date and time – Representations for Information interchange – Part 1: Basic rules
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
EN ISO 7405:2018 (ISO 7405:2018)	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-2:2022 (ISO 10993-2:2022)	Biological evaluation of medical devices - Part 2: Animal welfare requirements
EN ISO 10993-3:2014 (ISO 10993-3:2014)	Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016 (ISO 10993-6:2016)	Biological Evaluation of Medical Devices - Part 6: Tests for local effects after implantation
EN ISO 10993-10:2023 (ISO 10993-10:2021)	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-11:2018 (ISO 10993-11:2017)	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021 (ISO 10993-12:2021)	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-23:2021 (ISO 10993-23:2021)	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 10993-17:2023 (ISO 10993-17:2023)	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
MDCG 2020-7	Post-Market clinical follow-up (PMCF) plan template
MDCG 2019-9	Summary of safety and clinical performance
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745

OptiBond FL – Applicable Standards Attachment 2 to Annex IV EU Declaration of Conformity	
Standard	**Title**
MDCG 2023-3	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices
MEDDEV 2.7/1 Rev4	Clinical Evaluation: A Guide For Manufacturers And Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/2 Rev2	Guidance document medical devices - Market surveillance – Post Market Clinical Follow-up studies
MDCG 2018-1	Guidance on basic UDI-DI and changes to UDI-DI
MDCG 2021-19	Guidance note integration of the UDI within an organization's quality management system
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2020-8	Guidance on Post Market Clinical Follow-up (PMCF) Evaluation Report Template
EN ISO 14971:2019 ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+A1:2020 (IEC 62366- 1:2015+AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems