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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 Universal 360, Technical File #R118
Basic UDI-DI:	805151187100011356
Product Tradename(s):	OptiBond Universal 360
Device Identification:	See Attachment 1
Classification and Rule(s):	IIa per Annex VIII, Rule 8
Intended Purpose:	OptiBond Universal 360 is an adhesive resin used to bond the tooth to various restorative materials such as composites, ceramics, metals, and endodontic posts. It is also be used for cavity sealer as a pre-treatment for indirect restorations.
Notified Body:	BSI Group The Netherlands B.V.
Notified Body Number:	2797
Conformity Assessment Procedure & Certificate issued:	Annex XI Part A – Production Quality Asurance 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 — Place

18-Sep-2025 | 19:59 CEST — Date of Issue

DocuSigned by:
Jennifer Evans
8DF30BF54362465...

Name: Jennifer Evans
Title: VP RA/QA Kerr Italia S.r.l.

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OptiBond Universal 360 – Technical File R009 and R118 Attachment 1 to Annex IV EU Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
36820	OptiBond Universal 360 Bottle Kit	805151187100011356
36821	OptiBond Universal 360 Unidose Kit	805151187100011356
36822	OptiBond Universal 360 Bottle Refill	805151187100011356
36823	OptiBond Universal 360 Unidose Sample	805151187100011356

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OptiBond Universal 360 – Applicable Standards Attachment 2 to Annex IV EU Declaration of Conformity	
Standard	**Title**
EN 1641:2009	Dentistry - Medical devices for dentistry - Materials
EN ISO 29022: 2013 (ISO 29022:2013)	Dentistry – Adhesive – Notched Edge Shear Bond Strength Test
EN ISO 13485:2016 EN ISO 13485/A11:2021 (ISO 13485: 2016)	Medical Devices – Quality management systems
EN ISO 20417:2021 (ISO 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

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OptiBond Universal 360 – Applicable Standards Attachment 2 to Annex IV EU Declaration of Conformity	
Standard	**Title**
EN ISO 14971:2019 EN ISO 14971:2019/A11:2021 (ISO 14971:2019)	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
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
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 2.12/1 Rev8	Guidelines on a Medical Devices Vigilance System
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 organisation's quality management system
MDCG 2021-24	Guidance on classification of medical devices
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems