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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:	SimpliShade Bulk Fill and SimpliShade Bulk Fill Flow, Technical File, R117
Basic UDI-DI:	805151187100011458
Product Tradename(s):	SimpliShade Bulk Fill Flow
Device Identification:	See Attachment 1
Classification and Rule(s):	Class IIa, Rule 8 (Annex VIII)
Intended Purpose:	The intended purpose of SimpliShade Bulk Fill Flow is for restoration of teeth with small cavities or small core build-ups and as a liner/base.
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.

Italy	28-Mar-2024 | 19:35 JST	DocuSigned by: Annabella Del Pozzo 652DDD4BAE86418...
Place	Date of Issue	Name: Annabella Del Pozzo Title: Sr. Quality Systems & EHS Manager

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SimpliShade Bulk Fill Flow – Technical File R117 Attachment 1 to Annex IV EU Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
37217	SimpliShade Bulk Fill Flow Syringe	805151187100011458
37218	SimpliShade Bulk Fill Flow Unidose 20 Pack	805151187100011458
37219	SimpliShade Bulk Fill Flow Syringe, Sample	805151187100011458
37220	SimpliShade Bulk Fill Flow Unidose, Sample, 3 Pack	805151187100011458

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SimpliShade Bulk Fill Flow – Applicable Standards Attachment 2 to Annex IV Declaration of Conformity	
Standard	**Title**
EN ISO 6874:2015 (ISO 6874:2015)	Dentistry – Polymer-based pit and fissure sealant
EN ISO 29022:2013 (ISO 29022:2013)	Dentistry – Adhesion – Notched-edge shear bond strength test
EN ISO 7491:2000 (ISO 7491:2000)	Dental materials – Determination of colour stability
EN 1641:2009	Dentistry - Medical devices for dentistry - Materials
ISO 4049:2019 (Partial)	Dentistry-Polymer-based filling, restorative and luting materials
EN ISO 13485:2016+A11:2021 (ISO 13485:2016)	Medical Devices - Quality management systems
EN ISO 14971:2019, EN ISO 14971:2019/ A11:2021 (ISO 14971:2019)	Medical devices - Application of risk management to medical devices
EN ISO 20417:2021 (ISO 20417:2021)	Medical Devices - Information to be supplied by the manufacturer
ISO 8601-1:2019	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 62366-1:2015+A1:2020 (IEC 62366-1:2015+AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
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 10993-2:2006)	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 10993-10:2021 (ISO 10993-10:2010)	Biological evaluation of medical devices - Part 10: Tests for skin sensitization

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SimpliShade Bulk Fill Flow – Applicable Standards Attachment 2 to Annex IV Declaration of Conformity	
Standard	**Title**
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 10993-17:2023 (ISO 10993-17:2023)	Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-23:2021 (ISO 10993-23:2021)	Biological evaluation of medical devices - Part 23: Tests for irritation
MDCG 2021-24	Guidance on classification of medical devices
MEDDEV 2.7/1 Rev 4 (June 2016)	Clinical Evaluations: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/1 Rev 8	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/2 Rev 2	Post Market Clinical Follow-up Studies
MDCG 2020-1	Guidance on Clinical Evaluation (MDR)
MDCG 2020-5	Guidance on Clinical Evaluation – Equivalence
MDCG 2020-7	Guidance on Post-Market Clinical Follow-up (PMCF) Plan Template
MDCG 2020-8	Guidance on Post-Market Clinical Follow-up (PMCF) Evaluation Report Template
MDCG 2019-9	Guidance on Summary of safety and clinical performance
MDCG 2020-13	Guidance on Clinical evaluation assessment report template
MDCG 2023-3	Guidance on Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
ASTM D4169:2022	Standard Practice for Performance Testing of Shipping Containers and Systems