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:	SimpliShade Bulk Fill and SimpliShade Bulk Fill Flow, Technical File, R117
Basic UDI-DI:	805151187100011458
Product Tradename(s):	SimpliShade Bulk Fill
Device Identification:	See Attachment 1
Classification and Rule(s):	Class IIa, Rule 8 (Annex VIII)
Intended Purpose:	The intended purpose of SimpliShade Bulk Fill is for restoration of teeth or as a core build-up material.
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 IST	DocuSigned by: Annabella Del Pozzo 652DDD4BAE86418...
Place	Date of Issue	Name: Annabella Del Pozzo Title: Sr. Quality Systems & EHS Manager

SimpliShade Bulk Fill – Technical File R117 Attachment 1 to Annex IV EU Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
37211	SimpliShade Bulk Fill Syringe	805151187100011458
37212	SimpliShade Bulk Fill Unidose 20-Pack	805151187100011458
37213	SimpliShade Bulk Fill Syringe, Sample	805151187100011458
37214	SimpliShade Bulk Fill Unidose, Sample, 3 Pack	805151187100011458

SimpliShade Bulk Fill– Applicable Standards Attachment 2 to Annex IV Declaration of Conformity	
Standard	**Title**
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
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

SimpliShade Bulk Fill– Applicable Standards Attachment 2 to Annex IV Declaration of Conformity	
Standard	**Title**
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