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Annex IV MDR 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:	Maxcem Elite, Technical File R021
Basic UDI-DI:	80515118710000395K
Product Tradename(s):	Maxcem Elite
Device Identification:	See Attachment 1
Classification and Rule(s):	Class IIa, Rule 8 (per Annex VIII)
Intended Purpose:	The intended purpose of Maxcem Elite is for the cementation of all types of restorations 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.

Brea, CA USA	03-Jun-2024 | 03:59 CEST	DocuSigned by: Jennifer Evans 8DF30BF54362465...
Place	Date of Issue	Name: Jennifer Evans Title: VP, RA/QA

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Maxcem Elite – Technical File R021 Attachment 1 to Annex IV MDR Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
34055	Maxcem Elite Standard Kit	80515118710000395K
34056	Maxcem Elite Value Kit	80515118710000395K
34057	Maxcem Elite Mini Kit	80515118710000395K
34058	Maxcem Elite Refill, Clear	80515118710000395K
34059	Maxcem Elite Refill, White	80515118710000395K
34060	Maxcem Elite Refill, White Opaque	80515118710000395K
34061	Maxcem Elite Refill, Yellow	80515118710000395K
36040	Maxcem Elite EU Sample	80515118710000395K

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Maxcem Elite – Applicable Standards Attachment 2 to Annex IV MDR Declaration of Conformity	
Standard	**Title**
EN 1641:2009	Dentistry - Medical devices for dentistry - Materials
EN ISO 4049:2019 (ISO 4049:2019)	Dentistry. Polymer-based restorative materials
ISO/TS 16506:2017	Dentistry – Polymer-based luting materials containing adhesive components
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 10993-2:2022)	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

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Maxcem Elite – Applicable Standards Attachment 2 to Annex IV MDR Declaration of Conformity	
Standard	**Title**
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
ASTM D4169:2022	Standard Practice for Performance Testing of Shipping Containers and Systems
MDCG 2021-24	Guidance on classification of medical devices
MEDDEV 2.7/1 Rev 4	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 2021-24	Guidance on classification of medical devices
MDCG 2020-1	Guidance on Clinical Evaluation (MDR)
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-7	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	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