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Annex XI Part A 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:	Harmonize Project #1145 and Technical File #R011
Basic UDI-DI:	80515118710000195D
Product Tradename(s):	Harmonize
Device Identification:	See Attachment 1
Classification and Rule(s):	Class IIa – Rule 8 (per Annex VIII)
Intended Purpose:	The intended purpose of Harmonize is for restoration of teeth.
Notified Body:	BSI Group The Netherlands B.V.
Notified Body Number:	2797
Conformity Assessment Procedure & Certificate issued:	Annex XI Part A – Production Quality Assurance CE 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.

Place	Date of Issue	
Scafati, Italy	14-May-2024 | 01:51 JST	DocuSigned by: Annabella Del Pozzo 652DDD4BAE86418...
		Annabella Del Pozzo Sr. Quality Systems and EHS Manager

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Harmonize Project #1145 and Technical File #R011 Attachment 1 to Annex XI Part A EU Declaration of Conformity Part Number List (1 of 2)	
REF	**Device Description**
36536	Harmonize A2 Dentine Syringe Refill
36546	Harmonize A3 Dentine Syringe Refill
36548	Harmonize A4 Dentine Syringe Refill
36537	Harmonize A2 Enamel Syringe Refill
36553	Harmonize A3 Enamel Syringe Refill
36538	Harmonize Translucent Amber Incisal Syringe Refill
36569	Harmonize Translucent Clear Incisal Syringe Refill
36570	Harmonize Translucent Grey Incisal Syringe Refill
36545	Harmonize A1 Dentine Syringe Refill
36547	Harmonize A3.5 Dentine Syringe Refill
36549	Harmonize B3 Dentine Syringe Refill
36550	Harmonize C4 Dentine Syringe Refill
36551	Harmonize XL2 Dentine Syringe Refill
36552	Harmonize A1 Enamel Syringe Refill
36554	Harmonize A3.5 Enamel Syringe Refill
36555	Harmonize A4 Enamel Syringe Refill
36556	Harmonize B1 Enamel Syringe Refill
36557	Harmonize B2 Enamel Syringe Refill
36558	Harmonize B3 Enamel Syringe Refill
36559	Harmonize B4 Enamel Syringe Refill
36560	Harmonize C1 Enamel Syringe Refill
36561	Harmonize C2 Enamel Syringe Refill
36562	Harmonize C3 Enamel Syringe Refill
36563	Harmonize C4 Enamel Syringe Refill
36564	Harmonize D2 Enamel Syringe Refill
36565	Harmonize D3 Enamel Syringe Refill
36566	Harmonize D4 Enamel Syringe Refill
36567	Harmonize XL Enamel Syringe Refill
36568	Harmonize Translucent Blue Incisal Syringe Refill
36539	Harmonize Translucent SuperClear Incisal Syringe Refill
36571	Harmonize A1 Dentine Unidose Refill
36572	Harmonize A2 Dentine Unidose Refill
36573	Harmonize A3 Dentine Unidose Refill
36574	Harmonize A3.5 Dentine Unidose Refill
36575	Harmonize A4 Dentine Unidose Refill
36576	Harmonize B3 Dentine Unidose Refill
36577	Harmonize C4 Dentine Unidose Refill
36578	Harmonize XL2 Dentine Unidose Refill
36579	Harmonize A1 Enamel Unidose Refill
36542	Harmonize A2 Enamel Unidose Refill

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Harmonize Project #1145 and Technical File #R011 Attachment 1 to Annex XI Part A EU Declaration of Conformity Part Number List (2 of 2)	
REF	**Device Description**
36581	Harmonize A3 Enamel Unidose Refill
36582	Harmonize A3.5 Enamel Unidose Refill
36583	Harmonize A4 Enamel Unidose Refill
36584	Harmonize B1 Enamel Unidose Refill
36585	Harmonize B2 Enamel Unidose Refill
36586	Harmonize B3 Enamel Unidose Refill
36587	Harmonize B4 Enamel Unidose Refill
36588	Harmonize C1 Enamel Unidose Refill
36589	Harmonize C2 Enamel Unidose Refill
36590	Harmonize C3 Enamel Unidose Refill
36591	Harmonize C4 Enamel Unidose Refill
36592	Harmonize D2 Enamel Unidose Refill
36593	Harmonize D3 Enamel Unidose Refill
36594	Harmonize D4 Enamel Unidose Refill
36595	Harmonize XL Enamel Unidose Refill
36543	Harmonize Translucent Amber Incisal Unidose Refill
36597	Harmonize Translucent Blue Incisal Unidose Refill
36598	Harmonize Translucent Clear Incisal Unidose Refill
36599	Harmonize Translucent Grey Incisal Unidose Refill
36638	Harmonize Sample Syringe Pack
36653	Harmonize Sample Unidose Pack A2E and A3E
36631	Harmonize Trial Kit Syringe
36632	Harmonize Trial Kit Unidose
36633	Harmonize Intro Kit Syringe
36634	Harmonize Intro Kit Unidose
36635	Harmonize Advanced Kit Syringe

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Harmonize Project #1145 and Technical File #R011 Attachment 2 - Medical Device Standards Applied	
Standard	**Title**
EN 1641:2009	Dentistry - Medical devices for dentistry - Materials
ISO 4049:2019 EN ISO 4049:2019	Dentistry – Polymer-based Filling, Restorative and Luting Materials
ISO 6874:2015	Dentistry - Polymer-based pit and fissure sealants
EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021	Medical Devices - Quality management systems
ISO 20417:2021 EN 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
ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
ISO 7405:2018 EN ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
ISO 10993-1:2020 EN ISO 10993-1:2020	Biological Evaluation of Medical Devices - Part 1: Evaluation and testing
ISO 10993-2:2022 EN ISO 10993-2:2022	Biological Evaluation of Medical Devices - Part 2: Animal welfare requirements
ISO 10993-3:2014 EN ISO 10993-3:2014	Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009 EN ISO 10993-5:2009	Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016 EN ISO 10993-6:2016	Biological Evaluation of Medical Devices - Part 6: Tests for local effects after implantation
ISO 10993-10:2021 EN ISO 10993-10:2021	Biological Evaluation of Medical Devices - Part 10: Tests for skin sensitization
ISO 10993-11:2018 EN ISO 10993-11:2018	Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity
ISO 10993-12:2021 EN ISO 10993-12:2021	Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials
ISO 10993-17:2023 EN ISO 10993-17:2023	Biological Evaluation of Medical Devices - Part 17: Toxicological risk assessment of medical device constituents
ISO 10993-23:2021 EN ISO 10993-23:2021	Biological Evaluation of Medical Devices - Part 23: Tests for irritation
ISO 14971:2019 EN ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62366-1:2015 EN 62366-1:2015+A1:2020 IEC 62366-1:2015+AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
ASTM D4169:2022	Standard Practice for Performance Testing of Shipping Containers and Systems

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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 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 2019-9	Summary of safety and clinical performance