



Annex V EC Declaration of Conformity

Manufacturer Name and Address: Kerr Corporation
1717 W. Collins Ave.,
Orange, CA 92867, USA

Authorized Representative Name and Address: Kerr Italia S.r.l.
Via Passanti, 174
Scafati (SA) 84018, Italy

Technical File Name/Number: Harmonize/SimpliShade/OptiShade Technical File, R011

Product Tradename(s): Harmonize

Device Identification: See Attachment 1

Classification and Rule(s): IIa per Annex IX, Rule 8

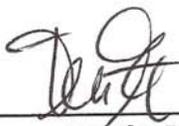
Notified Body: BSI Group The Netherlands B.V.
Notified Body Number: 2797
Conformity Assessment Procedure & Certificate Issued: Annex V – Production Quality Assurance
CE Certificate Number 00847

Declaration Statement:

We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

July 28, 2022
Issue date


Name: Jennifer Evans
Title: Vice President RA/QA - Consumables



**Harmonize – Attachment 1
to Annex V EC Declaration of Conformity**

REF	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



REF	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
36633	Harmonize Intro Kit Syringe
36634	Harmonize Intro Kit Unidose
36635	Harmonize Advanced Kit Syringe



MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCTION QUALITY ASSURANCE PROCEDURES

This is a declaration made under **Clause 6.6** of **Schedule 3** to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer Name:	Kerr Corporation
Business Address:	1717 W. Collins Ave., Orange, CA 92867, USA
Medical Device(s):	Harmonize
Classification:	Class IIa
GMDN Code and Term:	35870 – Dental Composite Resin
Scope of Application:	All lots

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

Production Quality Assurance Procedures Certificate:

Issued by British Standards Institution (BSI), Certificate No.: CE 00847 - Annex V of the Directive 93/42/EEC on Medical Devices.

Standards Applied:

- EN ISO 1641:2009 Dentistry - Medical devices for dentistry - Materials
- ISO 4049:2019 Dentistry-Polymer-based Filling, Restorative and Luting Materials
- EN ISO 13485:2016/AC:2018 Medical Devices - Quality management systems
- EN 1041:2008+A1 2013 Information supplied by the manufacturer of medical devices
- ISO 8601-1:2019 Date and time – Representations for Information interchange – Part 1: Basic rules
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
- EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing
- ISO 10993-2:2006 Biological evaluation of medical devices - Part 2: Animal welfare requirements



- EN ISO 10993-3:2014 Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016 Biological Evaluation of Medical Devices - Part 6: Tests for local effects after implantation
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- MEDDEV 2.7/1 Rev4 Clinical Evaluation: A Guide For Manufacturers And Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- ASTM D4169:2022 Standard Practice for Performance Testing of Shipping Containers and Systems

Authorised Signatory:

July 28, 2022
Issue date


Name: Jennifer Evans
Title: Vice President RA/QA - Consumables



Schedule for GMDN 35870 – Dental Composite Resin

REF	Description
36409	Harmonize XL Enamel Syringe Refill
36410	Harmonize A1 Enamel Syringe Refill
36411	Harmonize A2 Enamel Syringe Refill
36412	Harmonize A3 Enamel Syringe Refill
36413	Harmonize A3.5 Enamel Syringe Refill
36414	Harmonize A4 Enamel Syringe Refill
36415	Harmonize B1 Enamel Syringe Refill
36416	Harmonize B2 Enamel Syringe Refill
36417	Harmonize B3 Enamel Syringe Refill
36418	Harmonize B4 Enamel Syringe Refill
36419	Harmonize C1 Enamel Syringe Refill
36420	Harmonize C2 Enamel Syringe Refill
36421	Harmonize C3 Enamel Syringe Refill
36422	Harmonize C4 Enamel Syringe Refill
36423	Harmonize D2 Enamel Syringe Refill
36424	Harmonize D3 Enamel Syringe Refill
36425	Harmonize D4 Enamel Syringe Refill
36439	Harmonize XL Enamel Unidose Refill
36440	Harmonize A1 Enamel Unidose Refill
36441	Harmonize A2 Enamel Unidose Refill
36442	Harmonize A3 Enamel Unidose Refill
36443	Harmonize A3.5 Enamel Unidose Refill
36444	Harmonize A4 Enamel Unidose Refill
36445	Harmonize B1 Enamel Unidose Refill
36446	Harmonize B2 Enamel Unidose Refill
36447	Harmonize B3 Enamel Unidose Refill
36448	Harmonize B4 Enamel Unidose Refill
36449	Harmonize C1 Enamel Unidose Refill
36450	Harmonize C2 Enamel Unidose Refill
36451	Harmonize C3 Enamel Unidose Refill
36452	Harmonize C4 Enamel Unidose Refill
36453	Harmonize D2 Enamel Unidose Refill
36454	Harmonize D3 Enamel Unidose Refill
36455	Harmonize D4 Enamel Unidose Refill
36402	Harmonize A1 Dentin Syringe Refill
36403	Harmonize A2 Dentin Syringe Refill
36404	Harmonize A3 Dentin Syringe Refill



REF	Description
36405	Harmonize A3.5 Dentin Syringe Refill
36406	Harmonize A4 Dentin Syringe Refill
36407	Harmonize B3 Dentin Syringe Refill
36408	Harmonize C4 Dentin Syringe Refill
36426	Harmonize XL2 Dentin Syringe Refill
36432	Harmonize A1 Dentin Unidose Refill
36433	Harmonize A2 Dentin Unidose Refill
36434	Harmonize A3 Dentin Unidose Refill
36435	Harmonize A3.5 Dentin Unidose Refill
36436	Harmonize A4 Dentin Unidose Refill
36437	Harmonize B3 Dentin Unidose Refill
36438	Harmonize C4 Dentin Unidose Refill
36456	Harmonize XL2 Dentin Unidose Refill
36427	Harmonize Translucent Amber Syringe Refill
36428	Harmonize Translucent Blue Syringe Refill
36429	Harmonize Translucent Clear Syringe Refill
36430	Harmonize Translucent Gray Syringe Refill
36431	Harmonize Translucent Super Clear Syringe Refill
36512	Harmonize Translucent Amber Unidose Refill
36513	Harmonize Translucent Blue Unidose Refill
36514	Harmonize Translucent Clear Unidose Refill
36515	Harmonize Translucent Gray Unidose Refill
36883	Harmonize Shade Guide