



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: Premise Technical File, R095

Product Tradename(s): Premise

Device Identification: See Attachment 1

Classification and Rule(s): Ila 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:

April 7, 2022

Issue date

Name: Jennifer Evans

Title: Vice President RA/QA - Consumables



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

REF	Description
32712	Premise Refill Syringe Enamel A1
32713	Premise Refill Syringe Enamel A2
32714	Premise Refill Syringe Enamel A3
32715	Premise Refill Syringe Enamel A3.5
32716	Premise Refill Syringe Enamel A4
32717	Premise Refill Syringe Enamel B1
32718	Premise Refill Syringe Enamel B2
32719	Premise Refill Syringe Enamel B3
32720	Premise Refill Syringe Enamel B4
32721	Premise Refill Syringe Enamel C1
32722	Premise Refill Syringe Enamel C2
32723	Premise Refill Syringe Enamel C3
32724	Premise Refill Syringe Enamel C4
32725	Premise Refill Syringe Enamel D2
32726	Premise Refill Syringe Enamel D3
32727	Premise Refill Syringe Enamel D4
32728	Premise Refill Syringe Enamel XL1
32729	Premise Refill Syringe Enamel XL2
32730	Premise Refill Syringe Dentine A2
32731	Premise Refill Syringe Dentine A3
32732	Premise Refill Syringe Dentine A3.5
32733	Premise Refill Syringe Dentine A4
32734	Premise Refill Syringe Dentine B1
32735	Premise Refill Syringe Dentine B2
32736	Premise Refill Syringe Dentine C2
32737	Premise Refill Syringe Dentine D2
32738	Premise Refill Syringe Translucent Amber
32739	Premise Refill Syringe Translucent Grey
32740	Premise Refill Syringe Translucent Clear
32741	Premise Refill Syringe Translucent Super Clear
32745	Premise Refill Unidose Enamel A1
32746	Premise Refill Unidose Enamel A2
32747	Premise Refill Unidose Enamel A3
32748	Premise Refill Unidose Enamel A3.5
32749	Premise Refill Unidose Enamel A4
32750	Premise Refill Unidose Enamel B1
32751	Premise Refill Unidose Enamel B2
32752	Premise Refill Unidose Enamel B3
32753	Premise Refill Unidose Enamel B4
32754	Premise Refill Unidose Enamel C1
32755	Premise Refill Unidose Enamel C2



REF	Description
32756	Premise Refill Unidose Enamel C3
32757	Premise Refill Unidose Enamel C4
32758	Premise Refill Unidose Enamel D2
32759	Premise Refill Unidose Enamel D3
32760	Premise Refill Unidose Enamel D4
32761	Premise Refill Unidose Enamel XL1
32762	Premise Refill Unidose Enamel XL2
32763	Premise Refill Unidose Dentine A2
32764	Premise Refill Unidose Dentine A3
32765	Premise Refill Unidose Dentine A3.5
32766	Premise Refill Unidose Dentine A4
32767	Premise Refill Unidose Dentine B1
32768	Premise Refill Unidose Dentine B2
32769 E	Premise Refill Unidose Dentine C2
32770	Premise Refill Unidose Dentine D2
32771	Premise Refill Unidose Translucent Amber
32772	Premise Refill Unidose Translucent Grey
32773	Premise Refill Unidose Translucent Clear
32774	Premise Refill Unidose Translucent Super Clear
35372	Premise Syringe Mini Kit



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):	Premise
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
- EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- EN ISO 10993-12:2012 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
- 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 D4169:2016 Standard Practice for Performance Testing of Shipping Containers and Systems

Authorised Signatory:


Issue date



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



Schedule for GMDN 35870 – Dental Composite Resin

REF	Description
32617	Premise Refill Syringe Body Shade A1
32618	Premise Refill Syringe Body Shade A2
32619	Premise Refill Syringe Body Shade A3
32620	Premise Refill Syringe Body Shade A3.5
32621	Premise Refill Syringe Body Shade A4
32622	Premise Refill Syringe Body Shade B1
32623	Premise Refill Syringe Body Shade B2
32624	Premise Refill Syringe Body Shade B3
32625	Premise Refill Syringe Body Shade B4
32626	Premise Refill Syringe Body Shade C1
32627	Premise Refill Syringe Body Shade C2
32628	Premise Refill Syringe Body Shade C3
32629	Premise Refill Syringe Body Shade C4
32630	Premise Refill Syringe Body Shade D2
32631	Premise Refill Syringe Body Shade D3
32632	Premise Refill Syringe Body Shade D4
32633	Premise Refill Syringe Body Shade XL1
32634	Premise Refill Syringe Body Shade XL2
32635	Premise Refill Syringe Opaque Shade A2
32636	Premise Refill Syringe Opaque Shade A3
32637	Premise Refill Syringe Opaque Shade A3.5
32638	Premise Refill Syringe Opaque Shade A4
32639	Premise Refill Syringe Opaque Shade B1
32640	Premise Refill Syringe Opaque Shade B2
32641	Premise Refill Syringe Opaque Shade C2
32642	Premise Refill Syringe Opaque Shade D2
32643	Premise Refill Syringe Translucent Shade Amber
32644	Premise Refill Syringe Translucent Shade Grey
32645	Premise Refill Syringe Translucent Shade Clear
32646	Premise Refill Syringe Translucent Shade Super Clear
32870	Premise Refill Syringe Packable Shade A2
32647	Premise Refill Syringe Packable Shade A3
32648	Premise Refill Syringe Packable Shade A3.5
32649	Premise Refill Syringe Packable Shade A4
32650	Premise Refill Unidose Body Shade A1
32651	Premise Refill Unidose Body Shade A2
32652	Premise Refill Unidose Body Shade A3
32653	Premise Refill Unidose Body Shade A3.5
32654	Premise Refill Unidose Body Shade A4
32655	Premise Refill Unidose Body Shade B1
32656	Premise Refill Unidose Body Shade B2
32657	Premise Refill Unidose Body Shade B3
32658	Premise Refill Unidose Body Shade B4



REF	Description
32659	Premise Refill Unidose Body Shade C1
32660	Premise Refill Unidose Body Shade C2
32661	Premise Refill Unidose Body Shade C3
32662	Premise Refill Unidose Body Shade C4
32663	Premise Refill Unidose Body Shade D2
32664	Premise Refill Unidose Body Shade D3
32665	Premise Refill Unidose Body Shade D4
32666	Premise Refill Unidose Body Shade XL1
32667	Premise Refill Unidose Body Shade XL2
32668	Premise Refill Unidose Opaque Shade A2
32669	Premise Refill Unidose Opaque Shade A3
32670	Premise Refill Unidose Opaque Shade A3.5
32671	Premise Refill Unidose Opaque Shade A4
32672	Premise Refill Unidose Opaque Shade B1
32673	Premise Refill Unidose Opaque Shade B2
32674	Premise Refill Unidose Opaque Shade C2
32675	Premise Refill Unidose Opaque Shade D2
32676	Premise Refill Unidose Translucent Shade Amber
32677	Premise Refill Unidose Translucent Shade Grey
32678	Premise Refill Unidose Translucent Shade Clear
32679	Premise Refill Unidose Translucent Shade Super Clear
32871	Premise Refill Unidose Packable Shade A2
32680	Premise Refill Unidose Packable Shade A3
32681	Premise Refill Unidose Packable Shade A3.5
32682	Premise Refill Unidose Packable Shade A4
33346	Premise Unidose Sample Pack
33347	Premise Custom Syringe Kit
33348	Premise Custom Unidose Kit
32611	Premise Master Syringe Kit
32612	Premise Master Unidose Kit