



**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:** Herculite XRV/Classic Technical File, R091

**Product Tradename(s):** Herculite XRV

**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



**Herculite XRV – Attachment 1  
to Annex V EC Declaration of Conformity**

<b>REF</b>	<b>Description</b>
30893	Herculite XRV Esthetic Kit with OptiBond Solo Plus
30894	Herculite XRV General Kit with OptiBond Solo Plus
30895	Herculite XRV Unidose Kit with OptiBond Solo Plus
<b>Enamel Syringe Refill Packs</b>	
22859	Herculite XRV Syringe Enamel A1
22860	Herculite XRV Syringe Enamel A2
22861	Herculite XRV Syringe Enamel A3
22862	Herculite XRV Syringe Enamel A3.5
22863	Herculite XRV Syringe Enamel A4
22864	Herculite XRV Syringe Enamel B1
22865	Herculite XRV Syringe Enamel B2
22866	Herculite XRV Syringe Enamel B3
22867	Herculite XRV Syringe Enamel B4
22868	Herculite XRV Syringe Enamel C1
22869	Herculite XRV Syringe Enamel C2
22870	Herculite XRV Syringe Enamel C3
22871	Herculite XRV Syringe Enamel C4
22872	Herculite XRV Syringe Enamel D2
22873	Herculite XRV Syringe Enamel D3
22874	Herculite XRV Syringe Enamel D4
<b>Dentine Syringe Refill Packs</b>	
23391	Herculite XRV Syringe Dentine A1
22875	Herculite XRV Syringe Dentine A2
22876	Herculite XRV Syringe Dentine A3
22877	Herculite XRV Syringe Dentine A3.5
23390	Herculite XRV Syringe Dentine A4
22878	Herculite XRV Syringe Dentine B1
22879	Herculite XRV Syringe Dentine B2
23389	Herculite XRV Syringe Dentine B3
23388	Herculite XRV Syringe Dentine B4
23387	Herculite XRV Syringe Dentine C1
22880	Herculite XRV Syringe Dentine C2
23386	Herculite XRV Syringe Dentine C3
23385	Herculite XRV Syringe Dentine C4
22881	Herculite XRV Syringe Dentine D2
23384	Herculite XRV Syringe Dentine D3
23392	Herculite XRV Syringe Dentine D4
<b>Incisal Syringe Refill Packs</b>	
22882	Herculite XRV Syringe Incisal Light
22883	Herculite XRV Syringe Incisal Medium
<b>Enamel Unidose Refill Packs</b>	
23036	Herculite XRV Unidose Enamel A1



REF	Description
23037	Herculite XRV Unidose Enamel A2
23038	Herculite XRV Unidose Enamel A3
23039	Herculite XRV Unidose Enamel A3.5
23040	Herculite XRV Unidose Enamel A4
23041	Herculite XRV Unidose Enamel B1
23042	Herculite XRV Unidose Enamel B2
23043	Herculite XRV Unidose Enamel B3
23044	Herculite XRV Unidose Enamel B4
23045	Herculite XRV Unidose Enamel C1
23046	Herculite XRV Unidose Enamel C2
23047	Herculite XRV Unidose Enamel C3
23048	Herculite XRV Unidose Enamel C4
23049	Herculite XRV Unidose Enamel D2
23050	Herculite XRV Unidose Enamel D3
23051	Herculite XRV Unidose Enamel D4
<b>Dentine Unidose Refill Packs</b>	
23052	Herculite XRV Unidose Dentine A2
23053	Herculite XRV Unidose Dentine A3
23054	Herculite XRV Unidose Dentine A3.5
23055	Herculite XRV Unidose Dentine B1
23056	Herculite XRV Unidose Dentine B2
23057	Herculite XRV Unidose Dentine C2
23058	Herculite XRV Unidose Dentine D2
<b>Incisal Unidose Refill Packs</b>	
23059	Herculite XRV Unidose Enamel Incisal Light
23060	Herculite XRV Unidose Enamel Incisal Medium
<b>Enamel East Europe Refill Packs</b>	
7722859	XRV Enamel East Europe A1
7722860	XRV Enamel East Europe A2
7722861	XRV Enamel East Europe A3
7722862	XRV Enamel East Europe A3.5
7722863	XRV Enamel East Europe A4
7722864	XRV Enamel East Europe B1
7722865	XRV Enamel East Europe B2
7722866	XRV Enamel East Europe B3
7722867	XRV Enamel East Europe B4
7722868	XRV Enamel East Europe C1
7722869	XRV Enamel East Europe C2
7722870	XRV Enamel East Europe C3
7722871	XRV Enamel East Europe C4
7722872	XRV Enamel East Europe D2
7722873	XRV Enamel East Europe D3
7722874	XRV Enamel East Europe D4
<b>Dentine East Europe Refill Packs</b>	
7723391	XRV Dentine East Europe A1



REF	Description
7722875	XRV Dentine East Europe A2
7722876	XRV Dentine East Europe A3
7722877	XRV Dentine East Europe A3.5
7723390	XRV Dentine East Europe A4
7722878	XRV Dentine East Europe B1
7722879	XRV Dentine East Europe B2
7723389	XRV Dentine East Europe B3
7722881	XRV Dentine East Europe D2
7723384	XRV Dentine East Europe D3
7723387	XRV Dentine East Europe C1
7722880	XRV Dentine East Europe C2
7723386	XRV Dentine East Europe C3
7723385	XRV Dentine East Europe C4
<b>Kit</b>	
62811	Herculite XRV Custom Kit
62829	Herculite XRV Mini Kit Syringe (Enamel A2, A3 & Dentin A3)
62830	Herculite XRV Mini Kit Syringe (Enamel A2, A3.5 & Dentin A2)
62831	Herculite XRV Mini Kit Syringe (Enamel A2, C3 & Dentin D3)



## 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.

<b>Manufacturer Name:</b>	Kerr Corporation
<b>Business Address:</b>	1717 W. Collins Ave., Orange, CA 92867, USA
<b>Medical Device(s):</b>	Herculite XRV
<b>Classification:</b>	Class IIa
<b>GMDN Code and Term:</b>	35870 – Dental Composite Resin
<b>Scope of Application:</b>	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:**

April 7, 2022  
Issue date

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



**Schedule for GMDN 35870 – Dental Composite Resin**

<b>Part No.</b>	<b>Description</b>
30889	Herculite XRV General Kit
30890	Herculite XRV Unidose Kit
29797	Herculite XRV Syringe Enamel A1
29798	Herculite XRV Syringe Enamel A2
29799	Herculite XRV Syringe Enamel A3
29800	Herculite XRV Syringe Enamel A3.5
29801	Herculite XRV Syringe Enamel A4
29802	Herculite XRV Syringe Enamel B1
29803	Herculite XRV Syringe Enamel B2
29804	Herculite XRV Syringe Enamel B3
29805	Herculite XRV Syringe Enamel B4
29806	Herculite XRV Syringe Enamel C1
29807	Herculite XRV Syringe Enamel C2
29808	Herculite XRV Syringe Enamel C3
29809	Herculite XRV Syringe Enamel C4
29810	Herculite XRV Syringe Enamel D2
29811	Herculite XRV Syringe Enamel D3
29812	Herculite XRV Syringe Enamel D4
29813	Herculite XRV Syringe Dentine A1
29814	Herculite XRV Syringe Dentine A2
29815	Herculite XRV Syringe Dentine A3
29816	Herculite XRV Syringe Dentine A3.5
29817	Herculite XRV Syringe Dentine A4
29818	Herculite XRV Syringe Dentine B1
29819	Herculite XRV Syringe Dentine B2
29820	Herculite XRV Syringe Dentine B3
29821	Herculite XRV Syringe Dentine B4
29822	Herculite XRV Syringe Dentine C1
29823	Herculite XRV Syringe Dentine C2
29824	Herculite XRV Syringe Dentine C3
29825	Herculite XRV Syringe Dentine C4
29826	Herculite XRV Syringe Dentine D2
29827	Herculite XRV Syringe Dentine D3
29828	Herculite XRV Syringe Dentine D4
29832	Herculite XRV Syringe Cervical Shade Red/Brown
29833	Herculite XRV Syringe Cervical Shade Gray/Brown
29834	Herculite XRV Syringe Cervical Shade Yellow/Brown
29829	Herculite XRV Syringe Incisal Light
29830	Herculite XRV Syringe Incisal Medium
29835	Herculite XRV Unidose Enamel A1
29836	Herculite XRV Unidose Enamel A2
29837	Herculite XRV Unidose Enamel A3



Part No.	Description
29838	Herculite XRV Unidose Enamel A3.5
29839	Herculite XRV Unidose Enamel A4
29840	Herculite XRV Unidose Enamel B1
29841	Herculite XRV Unidose Enamel B2
29842	Herculite XRV Unidose Enamel B3
29843	Herculite XRV Unidose Enamel B4
29844	Herculite XRV Unidose Enamel C1
29845	Herculite XRV Unidose Enamel C2
29846	Herculite XRV Unidose Enamel C3
29847	Herculite XRV Unidose Enamel C4
29848	Herculite XRV Unidose Enamel D2
29849	Herculite XRV Unidose Enamel D3
29850	Herculite XRV Unidose Enamel D4
29851	Herculite XRV Unidose Dentine A2
29852	Herculite XRV Unidose Dentine A3
29853	Herculite XRV Unidose Dentine A3.5
29854	Herculite XRV Unidose Dentine B1
29855	Herculite XRV Unidose Dentine B2
29856	Herculite XRV Unidose Dentine C2
29857	Herculite XRV Unidose Dentine D2
29858	Herculite XRV Unidose Incisal Light
29859	Herculite XRV Unidose Incisal Medium