



#### Annex V EC Declaration of Conformity

<b>Manufacturer Name and Address:</b>	Kerr Corporation 1717 W. Collins Ave., Orange, CA 92867, USA
<b>Authorized Representative Name and Address:</b>	Kerr Italia S.r.l. Via Passanti, 174 Scafati (SA) 84018, Italy
<b>Technical File Name/Number:</b>	Herculite XRV Ultra/SimpliShade/OptiShade Technical File, R092
<b>Product Tradename(s):</b>	Herculite XRV Ultra
<b>Device Identification:</b>	See Attachment 1
<b>Classification and Rule(s):</b>	Ila per Annex IX, Rule 8
<b>Notified Body:</b>	BSI Group The Netherlands B.V.
<b>Notified Body Number:</b>	2797
<b>Conformity Assessment</b>	Annex V – Production Quality Assurance
<b>Procedure &amp; Certificate Issued:</b>	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 Ultra – Attachment 1  
to Annex V EC Declaration of Conformity**

REF	Description
33856	Herculite XRV Ultra Standard Kit Syringe
33856 TK	Herculite XRV Ultra Standard Kit Syringe TRK
33857	Herculite XRV Ultra Standard Kit Unidose
33858	Herculite XRV Ultra Intro Kit Syringe
33859	Herculite XRV Ultra Intro Kit Unidose
33860	Herculite XRV Ultra Mini Kit Syringe with OptiBond Solo Plus
34071	Herculite XRV Ultra Mini Kit Unidose with OptiBond Solo Plus
<b>Enamel Syringe Refill Packs.</b>	
34001	Herculite XRV Ultra Enamel Syringe XL
34002	Herculite XRV Ultra Enamel Syringe A1
34003	Herculite XRV Ultra Enamel Syringe A2
34004	Herculite XRV Ultra Enamel Syringe A3
34005	Herculite XRV Ultra Enamel Syringe A3.5
34006	Herculite XRV Ultra Enamel Syringe A4
34007	Herculite XRV Ultra Enamel Syringe B1
34008	Herculite XRV Ultra Enamel Syringe B2
34009	Herculite XRV Ultra Enamel Syringe B3
34010	Herculite XRV Ultra Enamel Syringe B4
34011	Herculite XRV Ultra Enamel Syringe C1
34012	Herculite XRV Ultra Enamel Syringe C2
34013	Herculite XRV Ultra Enamel Syringe C3
34014	Herculite XRV Ultra Enamel Syringe C4
34015	Herculite XRV Ultra Enamel Syringe D2
34016	Herculite XRV Ultra Enamel Syringe D3
34017	Herculite XRV Ultra Enamel Syringe D4
34027	Herculite XRV Ultra Syringe Incisal Light
<b>Enamel Unidose Refill Packs.</b>	
34028	Herculite XRV Ultra Enamel Unidose XL
34029	Herculite XRV Ultra Enamel Unidose A1
34030	Herculite XRV Ultra Enamel Unidose A2
34031	Herculite XRV Ultra Enamel Unidose A3
34032	Herculite XRV Ultra Enamel Unidose A3.5
34033	Herculite XRV Ultra Enamel Unidose A4
34034	Herculite XRV Ultra Enamel Unidose B1
34035	Herculite XRV Ultra Enamel Unidose B2
34036	Herculite XRV Ultra Enamel Unidose B3
34037	Herculite XRV Ultra Enamel Unidose B4
34038	Herculite XRV Ultra Enamel Unidose C1
34039	Herculite XRV Ultra Enamel Unidose C2
34040	Herculite XRV Ultra Enamel Unidose C3
34041	Herculite XRV Ultra Enamel Unidose C4
34042	Herculite XRV Ultra Enamel Unidose D2





REF	Description
34043	Herculite XRV Ultra Enamel Unidose D3
34044	Herculite XRV Ultra Enamel Unidose D4
34054	Herculite XRV Ultra Unidose Incisal Light
<b>Dentine Syringe Refill Packs</b>	
34018	Herculite XRV Ultra Dentine Syringe A1
34019	Herculite XRV Ultra Dentine Syringe A2
34020	Herculite XRV Ultra Dentine Syringe A3
34021	Herculite XRV Ultra Dentine Syringe A3.5
34022	Herculite XRV Ultra Dentine Syringe B1
34023	Herculite XRV Ultra Dentine Syringe B2
34024	Herculite XRV Ultra Dentine Syringe C2
34025	Herculite XRV Ultra Dentine Syringe D2
34026	Herculite XRV Ultra Dentine Syringe D3
<b>Dentine Unidose Refill Packs</b>	
34045	Herculite XRV Ultra Dentine Unidose A1
34046	Herculite XRV Ultra Dentine Unidose A2
34047	Herculite XRV Ultra Dentine Unidose A3
34048	Herculite XRV Ultra Dentine Unidose A3.5
34049	Herculite XRV Ultra Dentine Unidose B1
34050	Herculite XRV Ultra Dentine Unidose B2
34051	Herculite XRV Ultra Dentine Unidose C2
34052	Herculite XRV Ultra Dentine Unidose D2
34053	Herculite XRV Ultra Dentine Unidose D3
<b>Incisal Refill Packs</b>	
35370	Herculite XRV Ultra Unidose Incisal Medium
35371	Herculite XRV Ultra Syringe Incisal Medium
<b>Enamel ME Syringe Refill Packs</b>	
35962	Herculite XRV Ultra Enamel Syringe A1 ME
35965	Herculite XRV Ultra Enamel Syringe A2 ME
35974	Herculite XRV Ultra Enamel Syringe A3 ME
35977	Herculite XRV Ultra Enamel Syringe B1 ME
36001	Herculite XRV Ultra Enamel Syringe A3.5 ME
36004	Herculite XRV Ultra Enamel Syringe B2 ME
<b>Dentine ME Syringe Refill Packs</b>	
35968	Herculite XRV Ultra Dentine Syringe A1 ME
35971	Herculite XRV Ultra Dentine Syringe A2 ME
36007	Herculite XRV Ultra Dentine Syringe A3.5 ME
36010	Herculite XRV Ultra Dentine Syringe B2 ME



## 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 Ultra, Herculite XRV Ultra
<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.

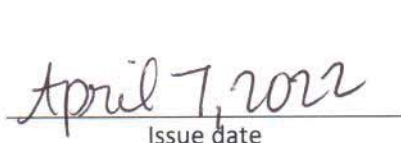
#### ***Standards Applied:***


- 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
- 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
34333	Herculite Ultra Intro Kit
Enamel Syringe Refill Packs.	
34336	Herculite Ultra Syringe XL
35491	Herculite Ultra Syringe XL2
34337	Herculite Ultra Enamel Syringe A1
34338	Herculite Ultra Enamel Syringe A2
34339	Herculite Ultra Enamel Syringe A3
34447	Herculite Ultra Enamel Syringe A3.5
34771	Herculite Ultra Enamel Syringe A4
34340	Herculite Ultra Enamel Syringe B1
34772	Herculite Ultra Enamel Syringe B2
35153	Herculite Ultra Enamel Syringe B3
35154	Herculite Ultra Enamel Syringe B4
34341	Herculite Ultra Enamel Syringe C1
34773	Herculite Ultra Enamel Syringe C2
34774	Herculite Ultra Enamel Syringe C3
35165	Herculite Ultra Enamel Syringe C4
34775	Herculite Ultra Enamel Syringe D2
35155	Herculite Ultra Enamel Syringe D3
35156	Herculite Ultra Enamel Syringe D4
Enamel Unidose Refill Packs.	
34346	Herculite Ultra Unidose XL
34347	Herculite Ultra Enamel Unidose A1
34348	Herculite Ultra Enamel Unidose A2
34349	Herculite Ultra Enamel Unidose A3
34448	Herculite Ultra Enamel Unidose 3.5
34776	Herculite Ultra Enamel Unidose A4
34350	Herculite Ultra Enamel Unidose B1
34777	Herculite Ultra Enamel Unidose B2
35159	Herculite Ultra Enamel Unidose B3
35160	Herculite Ultra Enamel Unidose B4
34351	Herculite Ultra Enamel Unidose C1
34778	Herculite Ultra Enamel Unidose C2
34779	Herculite Ultra Enamel Unidose C3
35166	Herculite Ultra Enamel Unidose C4
34780	Herculite Ultra Enamel Unidose D2
35161	Herculite Ultra Enamel Unidose D3
35162	Herculite Ultra Enamel Unidose D4
Dentine Syringe Refill Packs	
35487	Herculite Ultra Dentine Syringe A1
34342	Herculite Ultra Dentine Syringe A2
34343	Herculite Ultra Dentine Syringe A3
35626	Herculite Ultra Dentine Syringe A3.5
35488	Herculite Ultra Dentine Syringe A4
35157	Herculite Ultra Dentine Syringe B1
35489	Herculite Ultra Dentine Syringe B3
35627	Herculite Ultra Dentine Syringe C2
35490	Herculite Ultra Dentine Syringe C4
35628	Herculite Ultra Dentine Syringe D2
Dentine Unidose Refill Packs	
35499	Herculite Ultra Unidose XL2
35495	Herculite Ultra Dentine Unidose A1
34352	Herculite Ultra Dentine Unidose A2
34353	Herculite Ultra Dentine Unidose A3
35496	Herculite Ultra Dentine Unidose A4
35163	Herculite Ultra Dentine Unidose B1



REF	Description
35497	Herculite Ultra Dentine Unidose B3
35629	Herculite Ultra Dentine Unidose A3.5
35630	Herculite Ultra Dentine Unidose C2
35498	Herculite Ultra Dentine Unidose C4
35631	Herculite Ultra Dentine Unidose D2
<b>Incisal Refill Packs</b>	
34354	Herculite Ultra Unidose Incisal Light
34344	Herculite Ultra Syringe Incisal Light
<b>Sample</b>	
34392	Herculite Ultra Unidose Enamel Sample A2

REF	Description
33856	Herculite XRV Ultra Standard Kit Syringe
33856 TK	Herculite XRV Ultra Standard Kit Syringe TRK
33857	Herculite XRV Ultra Standard Kit Unidose
33858	Herculite XRV Ultra Intro Kit Syringe
33859	Herculite XRV Ultra Intro Kit Unidose
33860	Herculite XRV Ultra Mini Kit Syringe with OptiBond Solo Plus
34071	Herculite XRV Ultra Mini Kit Unidose with OptiBond Solo Plus
<b>Enamel Syringe Refill Packs.</b>	
34001	Herculite XRV Ultra Enamel Syringe XL
34002	Herculite XRV Ultra Enamel Syringe A1
34003	Herculite XRV Ultra Enamel Syringe A2
34004	Herculite XRV Ultra Enamel Syringe A3
34005	Herculite XRV Ultra Enamel Syringe A3.5
34006	Herculite XRV Ultra Enamel Syringe A4
34007	Herculite XRV Ultra Enamel Syringe B1
34008	Herculite XRV Ultra Enamel Syringe B2
34009	Herculite XRV Ultra Enamel Syringe B3
34010	Herculite XRV Ultra Enamel Syringe B4
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34014	Herculite XRV Ultra Enamel Syringe C4
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34016	Herculite XRV Ultra Enamel Syringe D3
34017	Herculite XRV Ultra Enamel Syringe D4
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<b>Enamel Unidose Refill Packs.</b>	
34028	Herculite XRV Ultra Enamel Unidose XL
34029	Herculite XRV Ultra Enamel Unidose A1
34030	Herculite XRV Ultra Enamel Unidose A2
34031	Herculite XRV Ultra Enamel Unidose A3
34032	Herculite XRV Ultra Enamel Unidose A3.5
34033	Herculite XRV Ultra Enamel Unidose A4
34034	Herculite XRV Ultra Enamel Unidose B1
34035	Herculite XRV Ultra Enamel Unidose B2
34036	Herculite XRV Ultra Enamel Unidose B3
34037	Herculite XRV Ultra Enamel Unidose B4
34038	Herculite XRV Ultra Enamel Unidose C1
34039	Herculite XRV Ultra Enamel Unidose C2
34040	Herculite XRV Ultra Enamel Unidose C3
34041	Herculite XRV Ultra Enamel Unidose C4
34042	Herculite XRV Ultra Enamel Unidose D2
34043	Herculite XRV Ultra Enamel Unidose D3
34044	Herculite XRV Ultra Enamel Unidose D4
34054	Herculite XRV Ultra Unidose Incisal Light
<b>Dentine Syringe Refill Packs</b>	





REF	Description
34018	Herculite XRV Ultra Dentine Syringe A1
34019	Herculite XRV Ultra Dentine Syringe A2
34020	Herculite XRV Ultra Dentine Syringe A3
34021	Herculite XRV Ultra Dentine Syringe A3.5
34022	Herculite XRV Ultra Dentine Syringe B1
34023	Herculite XRV Ultra Dentine Syringe B2
34024	Herculite XRV Ultra Dentine Syringe C2
34025	Herculite XRV Ultra Dentine Syringe D2
34026	Herculite XRV Ultra Dentine Syringe D3
<b>Dentine Unidose Refill Packs</b>	
34045	Herculite XRV Ultra Dentine Unidose A1
34046	Herculite XRV Ultra Dentine Unidose A2
34047	Herculite XRV Ultra Dentine Unidose A3
34048	Herculite XRV Ultra Dentine Unidose A3.5
34049	Herculite XRV Ultra Dentine Unidose B1
34050	Herculite XRV Ultra Dentine Unidose B2
34051	Herculite XRV Ultra Dentine Unidose C2
34052	Herculite XRV Ultra Dentine Unidose D2
34053	Herculite XRV Ultra Dentine Unidose D3
<b>Incisal Refill Packs</b>	
35370	Herculite XRV Ultra Unidose Incisal Medium
35371	Herculite XRV Ultra Syringe Incisal Medium
<b>Enamel ME Syringe Refill Packs</b>	
35962	Herculite XRV Ultra Enamel Syringe A1 ME
35965	Herculite XRV Ultra Enamel Syringe A2 ME
35974	Herculite XRV Ultra Enamel Syringe A3 ME
35977	Herculite XRV Ultra Enamel Syringe B1 ME
36001	Herculite XRV Ultra Enamel Syringe A3.5 ME
36004	Herculite XRV Ultra Enamel Syringe B2 ME
<b>Dentine ME Syringe Refill Packs</b>	
35968	Herculite XRV Ultra Dentine Syringe A1 ME
35971	Herculite XRV Ultra Dentine Syringe A2 ME
36007	Herculite XRV Ultra Dentine Syringe A3.5 ME
36010	Herculite XRV Ultra Dentine Syringe B2 ME