



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 Classic

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:

15 October 2021

Issue date

Name: Mark Dzendzel

Title: Director, Quality Assurance Systems



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

REF	Description
33076 E	Herculite Classic Kit
33076 TK	Herculite Classic Kit TRK
Enamel Syringe Refill Packs	
33077 E	Herculite Classic Syringe Enamel A1
33078 E	Herculite Classic Syringe Enamel A2
33079 E	Herculite Classic Syringe Enamel A3
33080 E	Herculite Classic Syringe Enamel A3.5
33081 E	Herculite Classic Syringe Enamel A4
33082 E	Herculite Classic Syringe Enamel B1
33083 E	Herculite Classic Syringe Enamel B2
33086 E	Herculite Classic Syringe Enamel C1
33087 E	Herculite Classic Syringe Enamel C2
33088 E	Herculite Classic Syringe Enamel C3
33089 E	Herculite Classic Syringe Enamel C4
33090 E	Herculite Classic Syringe Enamel D2
33091 E	Herculite Classic Syringe Enamel D3
Dentine Syringe Refill Packs	
33093 E	Herculite Classic Syringe Dentine A1
33094 E	Herculite Classic Syringe Dentine A2
33095 E	Herculite Classic Syringe Dentine A3
33096 E	Herculite Classic Syringe Dentine A3.5
33097 E	Herculite Classic Syringe Dentine A4
33098 E	Herculite Classic Syringe Dentine B1
Incisal Syringe Refill Packs	
33109 E	Herculite Classic Syringe Incisal Light
33110 E	Herculite Classic Syringe Incisal Medium
Enamel Unidose Refill Packs	
33114 E	Herculite Classic Unidose Enamel A1
33115 E	Herculite Classic Unidose Enamel A2
33116 E	Herculite Classic Unidose Enamel A3
33117 E	Herculite Classic Unidose Enamel A3.5
33118 E	Herculite Classic Unidose Enamel A4
33119 E	Herculite Classic Unidose Enamel B1
33120 E	Herculite Classic Unidose Enamel B2
33121 E	Herculite Classic Unidose Enamel B3
33123 E	Herculite Classic Unidose Enamel C1
33124 E	Herculite Classic Unidose Enamel C2
33125 E	Herculite Classic Unidose Enamel C3
33126 E	Herculite Classic Unidose Enamel C4
33127 E	Herculite Classic Unidose Enamel D2
33128 E	Herculite Classic Unidose Enamel D3
Dentine Unidose Refill Packs	



REF	Description
33130 E	Herculite Classic Unidose Dentine A2
33131 E	Herculite Classic Unidose Dentine A3
33132 E	Herculite Classic Unidose Dentine A3.5
33133 E	Herculite Classic Unidose Dentine B1
Incisal Unidose Refill Packs	
33137 E	Herculite Classic Unidose Incisal Light
33138 E	Herculite Classic Unidose Incisal Medium
Enamel ME Syringe Refill Packs	
35980	Herculite Classic Syringe Enamel A1 ME
35983	Herculite Classic Syringe Enamel A2 ME
35986	Herculite Classic Syringe Enamel A3 ME
35989	Herculite Classic Syringe Enamel B1 ME
36013	Herculite Classic Syringe Enamel A3.5 ME
36016	Herculite Classic Syringe Enamel B2 ME
Dentine ME Syringe Refill Packs	
35992	Herculite Classic Syringe Dentine A1 ME
35995	Herculite Classic Syringe Dentine A2 ME
36019	Herculite Classic Syringe Dentine A3.5 ME
36022	Herculite Classic Syringe Dentine B2 ME