

EG Konformitätserklärung für Medizinprodukte *EC Declaration of Conformity for medical devices*

Nach Anhang II.3 der EG Richtlinie für Medizinprodukte 93/42/EWG
According to annex II.3 of the Directive for medical devices 93/42/EEC

Hersteller/*Manufacturer:*
Adresse/*Address:*

Coltène/Whaledent AG
Feldwiesenstrasse 20
CH-9450 Altstätten

Wir erklären hiermit, dass das Produkt in alleiniger Verantwortung
Herewith we declare under our sole responsibility that the product

Produktname
product name

klassifiziert nach Anhang IX
der Richtlinie 93/42/EWG
*classified according to annex IX
Directive 93/42/EEC*

BRILLIANT EverGlow

Klasse/class **Ila**
Benannte Stelle CE0123
Notified Body CE0123
(TÜV Süd Product Service, Ridlerstr. 65; 80339 Munich)

UMDNS / GMDN codes: 16-736 / 38764

den einschlägigen Bestimmungen der nachfolgenden Richtlinie
complies with the relevant regulations of the following directive

Richtlinie 93/42/EWG vom 14. Juni 1993 über Medizinprodukte
Directive 93/42/EEC of June 14, 1993 for medical devices

und deren Umsetzung in nationale Gesetze entspricht.
and with the national laws adopted by Member States.

Konformitätserklärung ist gültig in Verbindung mit dem CE Zertifikat G1 029125 0023 Rev.01; gültig bis: 2024-05-26
Declaration of Conformity is valid in combination with the EC Certificate G1 029125 0023 Rev. 01, valid till: 2024-05-26

Anhang/Annex I: Liste der angewandten Normen / List of applied standards
Anhang/Annex II: Detaillierte Produktliste / Detailed list of products

Ausgabedatum / *Date of issue*

Altstätten, 25.05.2021



Martin Schaufelberger
General Manager Coltène/Whaledent AG / CEO Coltene Group
Name und Unterschrift des Befugten
Name and signature of authorized person

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Anhang I / Annex I :

BRILLIANT EverGlow

Standard number and year:	EN ISO 4049
Standard name:	Dentistry - Polymer-based restorative materials

Anhang II / Annex II :

BRILLIANT EverGlow	
REF	Beschreibung/Description
60019697	BRILLIANT EverGlow BL Syr.
60019698	BRILLIANT EverGlow A1/B1 Syr.
60019699	BRILLIANT EverGlow A2/B2 Syr.
60019700	BRILLIANT EverGlow A3/D3 Syr.
60019701	BRILLIANT EverGlow A3,5/B3 Syr.
60019702	BRILLIANT EverGlow C2/C3 Syr.
60019703	BRILLIANT EverGlow A4/C4 Syr.
60019704	BRILLIANT EverGlow Trans. Syr.
60019705	BRILLIANT EverGlow BL Trans. Syr.
60019706	BRILLIANT EverGlow BL Tips
60019707	BRILLIANT EverGlow A1/B1 Tips
60019708	BRILLIANT EverGlow A2/B2 Tips
60019709	BRILLIANT EverGlow A3/D3 Tips
60019710	BRILLIANT EverGlow A3,5/B3 Tips
60019716	BRILLIANT EverGlow C2/C3 Tips
60019717	BRILLIANT EverGlow A4/C4 Tips
60019718	BRILLIANT EverGlow Trans. Tips
60019719	BRILLIANT EverGlow BL Trans. Tips
60019720	BRILLIANT EverGlow Trial Kit Syr.
60019721	BRILLIANT EverGlow Trial Kit Tips
60019722	BRILLIANT EverGlow System Kit Syr.
60019723	BRILLIANT EverGlow System Kit Tips
60019726	BRILLIANT EverGlow Regular Kit Syr.
60019727	BRILLIANT EverGlow Regular Kit Tips
60019730	BRILLIANT EverGlow Anterior Kit 2L Syr.
60019731	BRILLIANT EverGlow Anterior Kit 2L Tips
60019732	BRILLIANT EverGlow Starter Kit Syr.
60019733	BRILLIANT EverGlow Starter Kit Tips
60019739	BRILLIANT EverGlow Sample Syr. A2/B2
60019740	BRILLIANT EverGlow Sample Syr. A3/D3
60019741	BRILLIANT EverGlow Sample Syr. Trans.
60019742	BRILLIANT EverGlow Sample 4 Tips
60019743	BRILLIANT EverGlow Opaque BL Syr.
60019744	BRILLIANT EverGlow Opaque A1 Syr.
60019745	BRILLIANT EverGlow Opaque A3 Syr.

BRILLIANT EverGlow	
REF	Beschreibung/Description
60019746	BRILLIANT EverGlow Opaque BL Tips
60019747	BRILLIANT EverGlow Opaque A1 Tips
60019748	BRILLIANT EverGlow Opaque A3 Tips
60019749	BRILLIANT EverGlow Sample Syr. Opaque A1
60019750	BRILLIANT EverGlow Sample 3 Tips Opaque
60019759	BRILLIANT EverGlow Sample 6 Tips
60020090	Restoration Highlight Kit Syr.
60020091	Restoration Highlight Kit Tips
60021836	BRILLIANT EverGlow Welcome Kit 3 Syr.
60021837	BRILLIANT EverGlow System Kit 7 Syr.
60021838	BRILLIANT EverGlow Opaque BL Syr. 4g
60021839	BRILLIANT EverGlow Opaque A1 Syr. 4g
60021840	BRILLIANT EverGlow Opaque A3 Syr. 4g
60021841	BRILLIANT EverGlow BL Syr. 4g
60021842	BRILLIANT EverGlow A1/B1 Syr. 4g
60021843	BRILLIANT EverGlow A2/B2 Syr. 4g
60021844	BRILLIANT EverGlow A3/D3 Syr. 4g
60021845	BRILLIANT EverGlow A3,5/B3 Syr. 4g
60021846	BRILLIANT EverGlow C2/C3 Syr. 4g
60021847	BRILLIANT EverGlow A4/C4 Syr. 4g
60021848	BRILLIANT EverGlow BL Trans Syr. 4g
60021849	BRILLIANT EverGlow Trans Syr. 4g
60021855	BRILLIANT EverGlow Sample Syr. A2/B2 LAM
60021921	BRILLIANT EverGlow Bleach Syr. 100 x 4g
60021922	BRILLIANT EverGlow A1/B1 Syr. 100 x 4g
60021923	BRILLIANT EverGlow A2/B2 Syr. 100 x 4g
60021924	BRILLIANT EverGlow A3/D3 Syr. 100 x 4g
60021925	BRILLIANT EverGlow A3,5/B3 Syr. 100 x 4g
60021926	BRILLIANT EverGlow C2/C3 Syr. 100 x 4g
60021927	BRILLIANT EverGlow A4/C4 Syr. 100 x 4g
60021928	BRILLIANT EverGlow Trans. Syr. 100 x 4g
60021929	BRILLIANT EverGlow BLTrans. Syr.100 x 4g
60021930	BRILLIANT EverGlow OBL Syr. 100 x 4g
60021931	BRILLIANT EverGlow OA1 Syr. 100 x 4g
60021932	BRILLIANT EverGlow OA3 Syr. 100 x 4g
60023042	BRILLIANT EverGlow Sample Tips A2/B2
60023817	BRILLIANT EverGlow White Bleach Translucent (WB Trans), Syringe, 1 x 3 g
60023818	BRILLIANT EverGlow Xtra White Bleach (XWB), Syringe, 1 x 3 g
60023819	BRILLIANT EverGlow Opaque A2 (OA2), Syringe, 1 x 3 g
60023820	BRILLIANT EverGlow Opaque A4 (OA4), Syringe, 1 x 3 g
60023821	BRILLIANT EverGlow White Bleach Translucent (WB Trans), Tips, 20 x 0.2 g
60023822	BRILLIANT EverGlow Xtra White Bleach (XWB), Tips, 20 x 0.2 g
60023823	BRILLIANT EverGlow Opaque A2 (OA2), Tips, 20 x 0.2 g
60023824	BRILLIANT EverGlow Opaque A2 (OA4), Tips, 20 x 0.2 g
60024082	BRILLIANT EverGlow Sample Tips New Shades, 6 x 0.2 g
60024083	BRILLIANT EverGlow White Bleach Translucent (WB Trans), Syringe, 1 x 4 g
60024084	BRILLIANT EverGlow Xtra White Bleach (XWB), Syringe, 1 x 4 g
60024085	BRILLIANT EverGlow Opaque A2 (OA2), Syringe, 1 x 4 g
60024086	BRILLIANT EverGlow Opaque A4 (OA4), Syringe, 1 x 4 g
60024151	BRILLIANT EverGlow Single Shade Kit, Syringes, 8 x 3 g
60024152	BRILLIANT EverGlow Single Shade Kit, Tips, 60 x 0.2 g
60024156	BRILLIANT EverGlow Pro Extention Kit, Syringes, 8 x 3 g

BRILLIANT EverGlow	
REF	Beschreibung/Description
60024157	BRILLIANT EverGlow Pro Extention Kit, Tips, 60 x 0.2 g
60024160	BRILLIANT EverGlow A1/B1, Tips EcoPack, 60 x 0.2 g
60024161	BRILLIANT EverGlow A2/B2, Tips EcoPack, 60 x 0.2 g
60024162	BRILLIANT EverGlow A3/D3, Tips EcoPack, 60 x 0.2 g
60024163	BRILLIANT EverGlow A3.5/B3, Tips EcoPack, 60 x 0.2 g
60024166	BRILLIANT EverGlow A1/B1, Syringes EcoPack, 5 x 3 g
60024167	BRILLIANT EverGlow A2/B2, Syringes EcoPack, 5 x 3 g
60024168	BRILLIANT EverGlow A3/D3, Syringes EcoPack, 5 x 3 g
60024169	BRILLIANT EverGlow A3.5/B3, Syringes EcoPack, 5 x 3 g