

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

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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:* Coltène/Whaledent AG  
Adresse/*Address:* 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 NG** Klasse/class **Ila**  
Benannte Stelle CE0123  
Notified Body CE0123  
(TÜV Süd Product Service, Ridlerstr. 65; 80339 Munich)

UMDNS / GMDN codes: 16-736 / 38764 (old: 35875)

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*

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

### Anhang I / Annex I :

#### Brilliant NG

<b>Standard number and year:</b>	EN ISO 4049
<b>Standard name:</b>	Dentistry - Polymer-based restorative materials

### Anhang II / Annex II :

Brilliant NG	
REF	Beschreibung/Description
8950 NG	BRILL. NG INTROKIT
8951 NG	BRILL. NG DENTIN A1/B1 4G
8952 NG	BRILL. NG DENTIN A2/B2 4G
8953 NG	BRILL. NG DENTIN A3/D3 4G
8954 NG	BRILL. NG DENTIN A3,5/B3 4G
8955 NG	BRILL. NG DENTIN A4/C4 4G
8956 NG	BRILL. NG DENTIN C2/C3 4G
8957 NG	BRILL. NG DENTIN BLEACH 4G
8960 NG	BRILL. NG ENAMEL A1/B1 4G
8961 NG	BRILL. NG ENAMEL A2/B2 4G
8962 NG	BRILL. NG ENAMEL A3/D3 4G
8963 NG	BRILL. NG ENAMEL A3,5/B3 4G
8964 NG	BRILL. NG ENAMEL C2/C3 4G
8967 NG	BRILL. NG DENTIN BLEACH 10X4G
8968 NG	BRILL. NG TRANSP. 4G
8969 NG	BRILL. NG TRANSP. 10X4G
8970 NG	BRILL. NG DENTIN A1/B1 10X4G
8971 NG	BRILL. NG DENTIN A2/B2 10X4G
8972 NG	BRILL. NG DENTIN A3/D3 10X4G
8973 NG	BRILL. NG DENTIN A3,5/B3 10X4G
8974 NG	BRILL. NG ENAMEL BLEACH 4G
8975 NG	BRILL. NG DENTIN A4/C4 10X4G
8976 NG	BRILL. NG ENAMEL A4/C4 4G
8977 NG	BRILL. NG DENTIN C2/C3 10X4G
8979 NG	BRILL. NG INTROKIT W/O SG
8980 NG	BRILL. NG ENAMEL A1/B1 10X4G
8981 NG	BRILL. NG ENAMEL A2/B2 10X4G
8982 NG	BRILL. NG ENAMEL A3/D3 10X4G
8983 NG	BRILL. NG ENAMEL A3,5/B3 10X4G
8984 NG	BRILL. NG ENAMEL C2/C3 10X4G
8985 NG	BRILL. NG ENAMEL A4/C4 10X4G
8986 NG	BRILL. NG ENAMEL BLEACH 10X4G
60013879	BRILL. NG KIT RU