

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

UMDNS / GMDN codes: 16-726 / 38649 (old: 40592)

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



Roland Streuf
Director RA/Q, Quality Control & Analytics
Name und Unterschrift des Befugten
Name and signature of authorized person

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Anhang I / Annex I :

BRILLIANT Crios

Standard number and year:	No standard for this class of products available.
Standard name:	n.a

Anhang II / Annex II :

BRILLIANT Crios	
REF	Beschreibung/Description
60019985	BRILLIANT Crios Bleach LT 14 CEREC
60019986	BRILLIANT Crios A1 LT 14 CEREC
60019987	BRILLIANT Crios A2 LT 14 CEREC
60019988	BRILLIANT Crios A3 LT 14 CEREC
60019989	BRILLIANT Crios A3.5 LT 14 CEREC
60019990	BRILLIANT Crios B1 LT 14 CEREC
60019991	BRILLIANT Crios B2 LT 14 CEREC
60019992	BRILLIANT Crios B3 LT 14 CEREC
60019993	BRILLIANT Crios C2 LT 14 CEREC
60019994	BRILLIANT Crios A1 HT 14 CEREC
60019995	BRILLIANT Crios A2 HT 14 CEREC
60019996	BRILLIANT Crios A3 HT 14 CEREC
60019997	BRILLIANT Crios B1 HT 14 CEREC
60019998	BRILLIANT Crios Bleach LT 12 CEREC
60019999	BRILLIANT Crios A1 LT 12 CEREC
60020000	BRILLIANT Crios A2 LT 12 CEREC
60020001	BRILLIANT Crios A3 LT 12 CEREC
60020002	BRILLIANT Crios A3.5 LT 12 CEREC
60020003	BRILLIANT Crios B1 LT 12 CEREC
60020004	BRILLIANT Crios B2 LT 12 CEREC
60020005	BRILLIANT Crios B3 LT 12 CEREC
60020006	BRILLIANT Crios C2 LT 12 CEREC
60020007	BRILLIANT Crios A1 HT 12 CEREC
60020008	BRILLIANT Crios A2 HT 12 CEREC
60020009	BRILLIANT Crios A3 HT 12 CEREC
60020010	BRILLIANT Crios B1 HT 12 CEREC
60020011	BRILLIANT Crios Bleach LT 14 Planmill
60020012	BRILLIANT Crios A1 LT 14 Planmill
60020013	BRILLIANT Crios A2 LT 14 Planmill
60020014	BRILLIANT Crios A3 LT 14 Planmill
60020015	BRILLIANT Crios A3.5 LT 14 Planmill
60020016	BRILLIANT Crios B1 LT 14 Planmill
60020017	BRILLIANT Crios B2 LT 14 Planmill

60020018	BRILLIANT Crios B3 LT 14 Planmill
60020019	BRILLIANT Crios C2 LT 14 Planmill
60020020	BRILLIANT Crios A1 HT 14 Planmill
60020021	BRILLIANT Crios A2 HT 14 Planmill
60020022	BRILLIANT Crios A3 HT 14 Planmill
60020023	BRILLIANT Crios B1 HT 14 Planmill
60020037	BRILLIANT Crios Sample Kit CEREC, 1 pc
60020038	BRILLIANT Crios Sample Kit Planmill, 1 pc
60020095	BRILLIANT Crios Intro Kit CEREC 12
60020097	BRILLIANT Crios Intro Kit CEREC 14
60020099	BRILLIANT Crios Intro Kit Planmill 14
60022010	BRILLIANT Crios Welcome Kit, 1 pc
60022140	CAD/CAM Workshop Kit, 1 pc
60024174	BRILLIANT Crios Bleach ST 14 CEREC, 5 pcs
60024175	BRILLIANT Crios Universal ST 14 CEREC, 5 pcs