

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

UMDNS / GMDN codes: 16-336 / 35876

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 Coltene/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 COMPONEER

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

Anhang II / Annex II :

BRILLIANT COMPONEER	
REF	Beschreibung/Description
60023122	BRILLIANT COMPONEER Bleach Translucent S 11 (US 8), 1 pc
60023123	BRILLIANT COMPONEER Bleach Translucent S 12 (US 7), 1 pc
60023124	BRILLIANT COMPONEER Bleach Translucent S 13 (US 6), 1 pc
60023125	BRILLIANT COMPONEER Bleach Translucent S 21 (US 9), 1 pc
60023126	BRILLIANT COMPONEER Bleach Translucent S 22 (US 10), 1 pc
60023127	BRILLIANT COMPONEER Bleach Translucent S 23 (US 11), 1 pc
60023128	BRILLIANT COMPONEER Bleach Translucent M 11 (US 8), 1 pc
60023129	BRILLIANT COMPONEER Bleach Translucent M 12 (US 7), 1 pc
60023130	BRILLIANT COMPONEER Bleach Translucent M 13 (US 6), 1 pc
60023131	BRILLIANT COMPONEER Bleach Translucent M 21 (US 9), 1 pc
60023132	BRILLIANT COMPONEER Bleach Translucent M 22 (US 10), 1 pc
60023133	BRILLIANT COMPONEER Bleach Translucent M 23 (US 11), 1 pc
60023134	BRILLIANT COMPONEER Bleach Translucent L 11 (US 8), 1 pc
60023135	BRILLIANT COMPONEER Bleach Translucent L 12 (US 7), 1 pc
60023136	BRILLIANT COMPONEER Bleach Translucent L 13 (US 6), 1 pc
60023137	BRILLIANT COMPONEER Bleach Translucent L 21 (US 9), 1 pc
60023138	BRILLIANT COMPONEER Bleach Translucent L 22 (US 10), 1 pc
60023139	BRILLIANT COMPONEER Bleach Translucent L 23 (US 11), 1 pc
60023140	BRILLIANT COMPONEER Bleach Translucent XL 11 (US 8), 1 pc
60023141	BRILLIANT COMPONEER Bleach Translucent XL 12 (US 7), 1 pc
60023142	BRILLIANT COMPONEER Bleach Translucent XL 13 (US 6), 1 pc
60023143	BRILLIANT COMPONEER Bleach Translucent XL 21 (US 9), 1 pc
60023144	BRILLIANT COMPONEER Bleach Translucent XL 22 (US 10), 1 pc
60023145	BRILLIANT COMPONEER Bleach Translucent XL 23 (US 11), 1 pc
60023146	BRILLIANT COMPONEER Bleach Translucent S 31 (US 24), 1 pc
60023147	BRILLIANT COMPONEER Bleach Translucent S 32 (US 23), 1 pc
60023148	BRILLIANT COMPONEER Bleach Translucent S 33 (US 22), 1 pc
60023149	BRILLIANT COMPONEER Bleach Translucent S 41 (US 25), 1 pc
60023150	BRILLIANT COMPONEER Bleach Translucent S 42 (US 26), 1 pc
60023151	BRILLIANT COMPONEER Bleach Translucent S 43 (US 27), 1 pc
60023152	BRILLIANT COMPONEER Bleach Translucent M 31 (US 24), 1 pc
60023153	BRILLIANT COMPONEER Bleach Translucent M 32 (US 23), 1 pc
60023154	BRILLIANT COMPONEER Bleach Translucent M 33 (US 22), 1 pc

BRILLIANT COMPONEER	
REF	Beschreibung/Description
60023155	BRILLIANT COMPONEER Bleach Translucent M 41 (US 25), 1 pc
60023156	BRILLIANT COMPONEER Bleach Translucent M 42 (US 26), 1 pc
60023157	BRILLIANT COMPONEER Bleach Translucent M 43 (US 27), 1 pc
60023158	BRILLIANT COMPONEER Translucent S 11 (US 8), 1 pc
60023159	BRILLIANT COMPONEER Translucent S 12 (US 7), 1 pc
60023160	BRILLIANT COMPONEER Translucent S 13 (US 6), 1 pc
60023161	BRILLIANT COMPONEER Translucent S 21 (US 9), 1 pc
60023162	BRILLIANT COMPONEER Translucent S 22 (US 10), 1 pc
60023163	BRILLIANT COMPONEER Translucent S 23 (US 11), 1 pc
60023164	BRILLIANT COMPONEER Translucent M 11 (US 8), 1 pc
60023165	BRILLIANT COMPONEER Translucent M 12 (US 7), 1 pc
60023166	BRILLIANT COMPONEER Translucent M 13 (US 6), 1 pc
60023167	BRILLIANT COMPONEER Translucent M 21 (US 9), 1 pc
60023168	BRILLIANT COMPONEER Translucent M 22 (US 10), 1 pc
60023169	BRILLIANT COMPONEER Translucent M 23 (US 11), 1 pc
60023170	BRILLIANT COMPONEER Translucent L 11 (US 8), 1 pc
60023171	BRILLIANT COMPONEER Translucent L 12 (US 7), 1 pc
60023172	BRILLIANT COMPONEER Translucent L 13 (US 6), 1 pc
60023173	BRILLIANT COMPONEER Translucent L 21 (US 9), 1 pc
60023174	BRILLIANT COMPONEER Translucent L 22 (US 10), 1 pc
60023175	BRILLIANT COMPONEER Translucent L 23 (US 11), 1 pc
60023176	BRILLIANT COMPONEER Translucent XL 11 (US 8), 1 pc
60023177	BRILLIANT COMPONEER Translucent XL 12 (US 7), 1 pc
60023178	BRILLIANT COMPONEER Translucent XL 13 (US 6), 1 pc
60023179	BRILLIANT COMPONEER Translucent XL 21 (US 9), 1 pc
60023180	BRILLIANT COMPONEER Translucent XL 22 (US 10), 1 pc
60023181	BRILLIANT COMPONEER Translucent XL 23 (US 11), 1 pc
60023182	BRILLIANT COMPONEER Translucent S 31 (US 24), 1 pc
60023183	BRILLIANT COMPONEER Translucent S 32 (US 23), 1 pc
60023184	BRILLIANT COMPONEER Translucent S 33 (US 22), 1 pc
60023185	BRILLIANT COMPONEER Translucent S 41 (US 25), 1 pc
60023186	BRILLIANT COMPONEER Translucent S 42 (US 26), 1 pc
60023187	BRILLIANT COMPONEER Translucent S 43 (US 27), 1 pc
60023188	BRILLIANT COMPONEER Translucent M 31 (US 24), 1 pc
60023189	BRILLIANT COMPONEER Translucent M 32 (US 23), 1 pc
60023190	BRILLIANT COMPONEER Translucent M 33 (US 22), 1 pc
60023191	BRILLIANT COMPONEER Translucent M 41 (US 25), 1 pc
60023192	BRILLIANT COMPONEER Translucent M 42 (US 26), 1 pc
60023193	BRILLIANT COMPONEER Translucent M 43 (US 27), 1 pc
60023194	BRILLIANT COMPONEER Bleach Translucent S 14/24 (US 5/12), 2 pcs
60023195	BRILLIANT COMPONEER Bleach Translucent L 14/24 (US 5/12), 2 pcs
60023196	BRILLIANT COMPONEER Translucent S 14/24 (US 5/12), 2 pcs
60023197	BRILLIANT COMPONEER Translucent L 14/24 (US 5/12), 2 pcs
60023198	BRILLIANT COMPONEER Set Upper Jaw Bleach Translucent S, 6 pcs
60023200	BRILLIANT COMPONEER Set Upper Jaw Bleach Translucent M, 6 pcs
60023201	BRILLIANT COMPONEER Set Upper Jaw Bleach Translucent L, 6 pcs
60023203	BRILLIANT COMPONEER Set Upper Jaw Bleach Translucent XL, 6 pcs
60023204	BRILLIANT COMPONEER Set Upper Jaw Translucent S, 6 pcs
60023206	BRILLIANT COMPONEER Set Upper Jaw Translucent M, 6 pcs
60023207	BRILLIANT COMPONEER Set Upper Jaw Translucent L, 6 pcs

BRILLIANT COMPONEER	
REF	Beschreibung/Description
60023209	BRILLIANT COMPONEER Set Upper Jaw Translucent XL, 6 pcs
60023210	BRILLIANT COMPONEER Set Lower Jaw Bleach Translucent S, 6 pcs
60023211	BRILLIANT COMPONEER Set Lower Jaw Bleach Translucent M, 6 pcs
60023212	BRILLIANT COMPONEER Set Lower Jaw Translucent S, 6 pcs
60023213	BRILLIANT COMPONEER Set Lower Jaw Translucent M, 6 pcs
60023214	BRILLIANT COMPONEER Intro Kit Syringes, 28 pcs
60023215	BRILLIANT COMPONEER Intro Kit Tips, 28 pcs
60024473	BRILLIANT COMPONEER Intro Kit Syringes, 16 pcs