COLTENE

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

UMDNS / GMDN codes: 16-736 / 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 Certifcate 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 Produkteliste / 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* :

COMPONEER

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

Anhang II / *Annex II* :

COMPONEER	
REF	**Beschreibung/*Description***
1300	COMPONEER Premium System Kit Tips, 1 pc
1301	COMPONEER Premium System Kit Syringes, 1 pc
1304	COMPONEER Basic System Kit Tips, 1 pc
1305	COMPONEER Basic System Kit Syringes, 1 pc
1311	COMPONEER Set Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Teeth 11-13, 21-23, 6 pcs
1312	COMP. Set Upper Jaw, Size M, Shade Enamel White Opalescent (WO), Teeth 11-13, 21-23, 6 pcs
1313	COMP. Set Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Teeth 11-13, 21-23, 6 pcs
1314	COMPONEER Set Lower Jaw, Size S, Shade White Opalescent (WO), Teeth 31-33, 41-43, 6 pcs
1315	COMPONEER Set Lower Jaw, Size M, Shade White Opalescent (WO), Teeth 31-33, 41-43, 6 pcs
1316	COMPONEER Set Upper Jaw, Size S, Shade Enamel Universal, Teeth 11-13, 21-23, 6 pcs
1317	COMPONEER Set Upper Jaw, Size M, Shade Enamel Universal, Teeth 11-13, 21-23, 6 pcs
1318	COMPONEER Set Upper Jaw, Size L, Shade Enamel Universal, Teeth 11-13, 21-23, 6 pcs
1319	COMPONEER Set Lower Jaw, Size S, Shade Universal, Teeth 31-33, 41-43, 6 pcs
1320	COMPONEER Set Lower Jaw, Size M, Shade Universal, Teeth 31-33, 41-43, 6 pcs
1321	COMPONEER Refill Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 11, 2 pcs
1322	COMPONEER Refill Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 12, 2 pcs
1323	COMPONEER Refill Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 13, 2 pcs
1324	COMPONEER Refill Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 21, 2 pcs
1325	COMPONEER Refill Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 22, 2 pcs
1326	COMPONEER Refill Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 23, 2 pcs
1327	COMPONEER Refill Upper Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 11, 2 pcs
1328	COMPONEER Refill Upper Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 12, 2 pcs
1329	COMPONEER Refill Upper Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 13, 2 pcs
1330	COMPONEER Refill Upper Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 21, 2 pcs
1331	COMPONEER Refill Upper Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 22, 2 pcs
1332	COMPONEER Refill Upper Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 23, 2 pcs
1333	COMPONEER Refill Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Tooth 11, 2 pcs
1334	COMPONEER Refill Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Tooth 12, 2 pcs
1335	COMPONEER Refill Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Tooth 13, 2 pcs
1336	COMPONEER Refill Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Tooth 21, 2 pcs
1337	COMPONEER Refill Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Tooth 22, 2 pcs
1338	COMPONEER Refill Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Tooth 23, 2 pcs
1339	COMPONEER Refill Lower Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 31, 2 pcs
1340	COMPONEER Refill Lower Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 32, 2 pcs
1341	COMPONEER Refill Lower Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 33, 2 pcs

COMPONEER	
REF	**Beschreibung/*Description***
1342	COMPONEER Refill Lower Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 41, 2 pcs
1343	COMPONEER Refill Lower Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 42, 2 pcs
1344	COMPONEER Refill Lower Jaw, Size S, Shade Enamel White Opalescent (WO), Tooth 43, 2 pcs
1345	COMPONEER Refill Lower Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 31, 2 pcs
1346	COMPONEER Refill Lower Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 32, 2 pcs
1347	COMPONEER Refill Lower Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 33, 2 pcs
1348	COMPONEER Refill Lower Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 41, 2 pcs
1349	COMPONEER Refill Lower Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 42, 2 pcs
1350	COMPONEER Refill Lower Jaw, Size M, Shade Enamel White Opalescent (WO), Tooth 43, 2 pcs
1351	COMPONEER Refill Upper Jaw, Size S, Shade Enamel Universal, Tooth 11, 2 pcs
1352	COMPONEER Refill Upper Jaw, Size S, Shade Enamel Universal, Tooth 12, 2 pcs
1353	COMPONEER Refill Upper Jaw, Size S, Shade Enamel Universal, Tooth 13, 2 pcs
1354	COMPONEER Refill Upper Jaw, Size S, Shade Enamel Universal, Tooth 21, 2 pcs
1355	COMPONEER Refill Upper Jaw, Size S, Shade Enamel Universal, Tooth 22, 2 pcs
1356	COMPONEER Refill Upper Jaw, Size S, Shade Enamel Universal, Tooth 23, 2 pcs
1357	COMPONEER Refill Upper Jaw, Size M, Shade Enamel Universal, Tooth 11, 2 pcs
1358	COMPONEER Refill Upper Jaw, Size M, Shade Enamel Universal, Tooth 12, 2 pcs
1359	COMPONEER Refill Upper Jaw, Size M, Shade Enamel Universal, Tooth 13, 2 pcs
1360	COMPONEER Refill Upper Jaw, Size M, Shade Enamel Universal, Tooth 21, 2 pcs
1361	COMPONEER Refill Upper Jaw, Size M, Shade Enamel Universal, Tooth 22, 2 pcs
1362	COMPONEER Refill Upper Jaw, Size M, Shade Enamel Universal, Tooth 23, 2 pcs
1363	COMPONEER Refill Upper Jaw, Size L, Shade Enamel Universal, Tooth 11, 2 pcs
1364	COMPONEER Refill Upper Jaw, Size L, Shade Enamel Universal, Tooth 12, 2 pcs
1365	COMPONEER Refill Upper Jaw, Size L, Shade Enamel Universal, Tooth 13, 2 pcs
1366	COMPONEER Refill Upper Jaw, Size L, Shade Enamel Universal, Tooth 21, 2 pcs
1367	COMPONEER Refill Upper Jaw, Size L, Shade Enamel Universal, Tooth 22, 2 pcs
1368	COMPONEER Refill Upper Jaw, Size L, Shade Enamel Universal, Tooth 23, 2 pcs
1369	COMPONEER Refill Lower Jaw, Size S, Shade Enamel Universal, Tooth 31, 2 pcs
1370	COMPONEER Refill Lower Jaw, Size S, Shade Enamel Universal, Tooth 32, 2 pcs
1371	COMPONEER Refill Lower Jaw, Size S, Shade Enamel Universal, Tooth 33, 2 pcs
1372	COMPONEER Refill Lower Jaw, Size S, Shade Enamel Universal, Tooth 41, 2 pcs
1373	COMPONEER Refill Lower Jaw, Size S, Shade Enamel Universal, Tooth 42, 2 pcs
1374	COMPONEER Refill Lower Jaw, Size S, Shade Enamel Universal, Tooth 43, 2 pcs
1375	COMPONEER Refill Lower Jaw, Size M, Shade Enamel Universal, Tooth 31, 2 pcs
1376	COMPONEER Refill Lower Jaw, Size M, Shade Enamel Universal, Tooth 32, 2 pcs
1377	COMPONEER Refill Lower Jaw, Size M, Shade Enamel Universal, Tooth 33, 2 pcs
1378	COMPONEER Refill Lower Jaw, Size M, Shade Enamel Universal, Tooth 41, 2 pcs
1379	COMPONEER Refill Lower Jaw, Size M, Shade Enamel Universal, Tooth 42, 2 pcs
1380	COMPONEER Refill Lower Jaw, Size M, Shade Enamel Universal, Tooth 43, 2 pcs
60013998	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel White Opalescent (WO), Tooth 11, 2 pcs
60013999	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel White Opalescent (WO), Tooth 12, 2 pcs
60014000	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel White Opalescent (WO), Tooth 13, 2 pcs
60014001	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel White Opalescent (WO), Tooth 21, 2 pcs
60014002	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel White Opalescent (WO), Tooth 22, 2 pcs
60014003	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel White Opalescent (WO), Tooth 23, 2 pcs
60014004	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel Universal, Tooth 11, 2 pcs
60014005	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel Universal, Tooth 12, 2 pcs
60014006	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel Universal, Tooth 13, 2 pcs
60014007	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel Universal, Tooth 21, 2 pcs
60014008	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel Universal, Tooth 22, 2 pcs
60014009	COMPONEER Refill Upper Jaw, Size XL, Shade Enamel Universal, Tooth 23, 2 pcs
60014010	COMP. Set Upper Jaw, Size XL, Shade Enamel White Opalescent (WO), Teeth 11-13, 21-23, 6 pcs

COMPONEER	
REF	**Beschreibung/*Description***
60014012	COMP. Set Upper Jaw, Size XL, Shade Enamel Universal, Teeth 11-13, 21-23, 6 pcs
60014221	COMPONEER Intro System Kit Tips, 1 pc
60014222	COMPONEER Intro System Kit Syringes, 1 pc
60014392	COMPONEER Set Upper Jaw, Size S, Shade Enamel Universal, Teeth 14/24, 2 pcs
60014393	COMPONEER Set Upper Jaw, Size S, Shade Enamel White Opalescent (WO), Teeth 14/24, 2 pcs
60014394	COMPONEER Set Upper Jaw, Size L, Shade Enamel Universal, Teeth 14/24, 2 pcs
60014396	COMPONEER Set Upper Jaw, Size L, Shade Enamel White Opalescent (WO), Teeth 14/24, 2 pcs
60014500	COMP. Set Upper Jaw, Size M, Shade Dentin Bleach Opaque (Bl/O), Teeth 11-13, 21-23, 6 pcs
60014502	COMPONEER Refill Upper Jaw, Size M, Shade Dentin Bleach Opaque (Bl/O), Tooth 11, 2 pcs
60014504	COMPONEER Refill Upper Jaw, Size M, Shade Dentin Bleach Opaque (Bl/O), Tooth 12, 2 pcs
60014505	COMPONEER Refill Upper Jaw, Size M, Shade Dentin Bleach Opaque (Bl/O), Tooth 13, 2 pcs
60014506	COMPONEER Refill Upper Jaw, Size M, Shade Dentin Bleach Opaque (Bl/O), Tooth 21, 2 pcs
60014507	COMPONEER Refill Upper Jaw, Size M, Shade Dentin Bleach Opaque (Bl/O), Tooth 22, 2 pcs
60014508	COMPONEER Refill Upper Jaw, Size M, Shade Dentin Bleach Opaque (Bl/O), Tooth 23, 2 pcs
60014509	COMP. Set Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Teeth 11-13, 21-23, 6 pcs
60014510	COMP. Refill Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Tooth 11, 2 pcs
60014511	COMP. Refill Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Tooth 12, 2 pcs
60014512	COMP. Refill Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Tooth 13, 2 pcs
60014513	COMP. Refill Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Tooth 21, 2 pcs
60014514	COMP. Refill Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Tooth 22, 2 pcs
60014515	COMP. Refill Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Tooth 23, 2 pcs
60014516	COMP. Set Upper Jaw, Size XL, Shade Dentin Bleach Opaque (Bl/O), Teeth 11-13, 21-23, 6 pcs
60014517	COMPONEER Refill Upper Jaw, Size XL, Shade Dentin Bleach Opaque (Bl/O), Tooth 11, 2 pcs
60014518	COMPONEER Refill Upper Jaw, Size XL, Shade Dentin Bleach Opaque (Bl/O), Tooth 12, 2 pcs
60014519	COMPONEER Refill Upper Jaw, Size XL, Shade Dentin Bleach Opaque (Bl/O), Tooth 13, 2 pcs
60014520	COMPONEER Refill Upper Jaw, Size XL, Shade Dentin Bleach Opaque (Bl/O), Tooth 21, 2 pcs
60014521	COMPONEER Refill Upper Jaw, Size XL, Shade Dentin Bleach Opaque (Bl/O), Tooth 22, 2 pcs
60014522	COMPONEER Refill Upper Jaw, Size XL, Shade Dentin Bleach Opaque (Bl/O), Tooth 23, 2 pcs
60014523	COMPONEER Set Upper Jaw, Size L, Shade Dentin Bleach Opaque (Bl/O), Teeth 14/24, 2 pcs
60014524	COMPONEER Set Upper Jaw, Size S, Shade Dentin Bleach Opaque (Bl/O), Teeth 14/24, 2 pcs
60013806	COMPONEER DISPLAY
60013880	COMPONEER Workshop Veneer L11+L21
60013881	COMPONEER Workshop Veneer L13+L23
60013902	COMPONEER Model, Basic (with 6 Slightly Prepared Teeth
60013904	COMPONEER Model, baseplate
60013905	COMPONEER Model, Gingiva
60013908	COMPONEER Model, base Cover
60013909	COMPONEER Model, Posterior Tooth 14, Unprepared
60013910	COMPONEER Model, Posterior Tooth 24, Unprepared
60013911	COMPONEER Model, Anterior Tooth 11, Unprepared
60013913	COMPONEER Model, Anterior Tooth 12, Unprepared
60013914	COMPONEER Model, Anterior Tooth 13, Unprepared
60013915	COMPONEER Model, Anterior Tooth 21, Unprepared
60013916	COMPONEER Model, Anterior Tooth 22, Unprepared
60013917	COMPONEER Model, Anterior Tooth 23, Unprepared
60013918	COMPONEER Model, Anterior Set Teeth 11-13, 21-23, Unprepared
60013919	COMPONEER Model, Anterior Tooth 11, Slightly Prepared
60013920	COMPONEER Model, Anterior Tooth 12, Slightly Prepared
60013921	COMPONEER Model, Anterior Tooth 13, Slightly Prepared
60013922	COMPONEER Model, Anterior Tooth 21, Slightly Prepared
60013923	COMPONEER Model, Anterior Tooth 22, Slightly Prepared
60013924	COMPONEER Model, Anterior Tooth 23, Slightly Prepared

COMPONEER	
REF	**Beschreibung/*Description***
60013925	COMPONEER Model, Anterior Set Teeth 11-13, 21-23, Slightly Prepared
60013985	COMPONEER Workshop Veneer L12+L22
60014053	COMPONEER Model, Basic (with 4 Slightly Prepared Teeth)
60014088	COMPONEER Workshop Veneer L11-12 Universal, L21-22 WO
60018757	COMPONEER Premium Kit Packaging Tips, 1 pc
60018758	COMPONEER Premium Kit Packaging Syringes, 1 pc
60022959	Workshop Tooth Model Anterior, 1 pc
60022960	Workshop Tooth Model Posterior, 1 pc
60022968	Tooth Reposition Crown 36 for Workshop Tooth Model Posterior, 10 pcs
60022969	Tooth Reposition Class I Inlay 37 for Workshop Tooth Model Posterior, 10 pcs
60022970	Tooth Reposition Class II Onlay 36 for Workshop Tooth Model Posterior, 10 pcs
60022971	Tooth Reposition Class IV 11 for Workshop Tooth Model Anterior, 10 pcs
60022972	Tooth Reposition Veneer 11 for Workshop Tooth Model Anterior, 10 pcs
60022973	Tooth Reposition Veneer 21 for Workshop Tooth Model Anterior, 10 pcs
60022974	Unprepared Tooth 36 for Workshop Tooth Model Posterior, 10 pcs
60022975	Unprepared Tooth 21 for Workshop Tooth Model Anterior, 10 pcs
60022976	Unprepared Tooth 11 for Workshop Tooth Model Anterior, 10 pcs
60022977	Unprepared Tooth 37 for Workshop Tooth Model Posterior, 10 pcs