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*:	Dent4You AG
Adresse/*Address*:	St. Jakob Str. 37 CH-9000 St. Gallen

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

UMDNS / GMDN codes: 16-670 / ---

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 098596 0005 Rev.00.gültig bis: 2024-05-26
Declaration of Conformity is valid in combination with the EC Certifcate G1 098596 0005 Rev.00 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, 15.3.21

Roland Streuf
Director RA/Q, Quality Control & Analytics
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* :

FG Diamonds

Standard number and year:	SN EN ISO 1797:2017
Standard name:	Dentistry - Shanks for rotary and oscillating instruments

Standard number and year:	SN EN ISO 2157:2016
Standard name:	Dentistry - Nominal diameters and designation code numbers for rotary instruments

Standard number and year:	SN EN ISO 6360-1:2004 and AC: 2008
Standard name:	Dentistry – Number coding system for rotary instruments – Part 1: General characteristics

Standard number and year:	SN EN ISO 6360-2:2005 and A1 :2012
Standard name:	Dentistry – Number coding system for rotary instruments – Part 2: Shapes

Standard number and year:	SN EN ISO 6360-6:2004
Standard name:	Dentistry - Number coding system for rotary instruments – Part 6: Specific characteristics of abrasive instruments

Standard number and year:	SN EN ISO 7711-1:1999 and A1:2009
Standard name:	Dental rotary instruments – Diamond instruments – Part 1: Dimensions, requirements, marking and packaging

Standard number and year:	SN EN IS 7711-3:2005
Standard name:	Dentistry - Rotary diamond instruments - Part 3: Grit sizes, designation and colour code

Anhang II / *Annex II* :

FG Diamonds	
REF	**Beschreibung/*Description***
200004AC	G368-314-016-3.5-F
200005AC	G368-314-016-3.5-ML
200010AC	G368-314-020-5-F
200011AC	G368-314-020-5-ML
200014AC	G368-314-023-5-F
200015AC	G368-314-023-5-ML
200016AC	G368-314-023-5-MLX
200017AC	G368-314-023-5-UF
200018AC	G368-314-023-5-XF
200029AC	G379-314-016-3.5-F
200030AC	G379-314-016-3.5-ML
200037AC	G379-314-023-5-F
200038AC	G379-314-023-5-ML
200039AC	G379-314-023-5-MLX
200040AC	G379-314-023-5-UF
200041AC	G379-314-023-5-XF
200060AC	G6052-314-018-8-ML
200077AC	G801-314-009-ML
200079AC	G801-314-010-ML
200081AC	G801-314-012-ML
200083AC	G801-314-014-ML
200086AC	G801-314-016-ML
200088AC	G801-314-018-F
200089AC	G801-314-018-ML
200091AC	G801-314-018-UF
200092AC	G801-314-018-XF
200094AC	G801-314-020-ML
200095AC	G801-314-023-F
200096AC	G801-314-023-ML
200097AC	G801-314-023-MLX
200112AC	G805-314-012-0.9-ML
200113AC	G805-314-014-1.4-ML
200117AC	G805-314-023-2.1-ML
200121AC	G806-314-010-2.2-ML
200122AC	G806-314-012-2.2-ML
200124AC	G806-314-016-2.5-ML
200127AC	G807-314-012-3.5-ML
200131AC	G807-314-018-5-ML
200135AC	G811-314-033-5-ML
200136AC	G811-314-033-5-MLX
200137AC	G811-314-037-7-ML
200160AC	G830-314-010-2.7-ML
200162AC	G830-314-012-2.7-ML
200168AC	G830-314-016-2.7-ML
200177AC	G830L-314-012-4-ML
200180AC	G830L-314-014-5-ML
200201AC	G835-314-009-3-ML
200203AC	G835-314-010-4-ML

FG Diamonds	
REF	**Beschreibung/*Description***
200206AC	G835-314-012-4-ML
200208AC	G835-314-012-5-ML
200210AC	G835-314-014-4-ML
200211AC	G835-314-014-4-MLX
200217AC	G835R-314-008-3-ML
200219AC	G835R-314-010-4-ML
200221AC	G835R-314-012-4-ML
200223AC	G835R-314-014-4-ML
200227AC	G836-314-014-6-ML
200228AC	G836-314-014-6-MLX
200231AC	G836-314-018-6-ML
200239AC	G836R-314-010-6-ML
200241AC	G836R-314-012-6-ML
200250AC	G837-314-012-7-ML
200254AC	G837-314-014-8-ML
200257AC	G837-314-016-8-ML
200272AC	G838-314-009-3-ML
200273AC	G838-314-010-4-ML
200275AC	G838-314-012-4-ML
200278AC	G839-314-010-ML
200280AC	G839-314-012-ML
200282AC	G839-314-014-ML
200290AC	G845-314-012-4-ML
200304AC	G846-314-012-6-ML
200306AC	G846-314-016-6-ML
200308AC	G846-314-016-7-ML
200309AC	G846-314-016-7-MLX
200311AC	G846-314-018-7-ML
200313AC	G846-314-023-7-ML
200324AC	G847-314-012-8-ML
200326AC	G847-314-014-8-ML
200329AC	G847-314-016-8-ML
200330AC	G847-314-016-8-MLX
200332AC	G847-314-018-8-ML
200333AC	G847-314-018-8-MLX
200344AC	G848-314-014-10-ML
200345AC	G848-314-014-10-MLX
200347AC	G848-314-016-10-ML
200348AC	G848-314-016-10-MLX
200350AC	G848-314-018-10-ML
200351AC	G848-314-018-10-MLX
200354AC	G848-314-023-10-ML
200360AC	G848L-314-018-12-ML
200372AC	G850-314-012-10-ML
200373AC	G850-314-014-10-F
200374AC	G850-314-014-10-ML
200375AC	G850-314-016-10-ML
200381AC	G850-314-018-8-ML
200382AC	G850-314-018-8-MLX
200387AC	G850L-314-016-12-ML

FG Diamonds	
REF	**Beschreibung/*Description***
200388AC	G850L-314-018-12-ML
200398AC	G852-314-012-6-ML
200406AC	G853-314-008-3.5-ML
200414AC	G855-314-012-6-ML
200416AC	G855-314-014-6-ML
200417AC	G855-314-014-6-MLX
200433AC	G856-314-012-8-ML
200435AC	G856-314-014-8-ML
200436AC	G856-314-014-9-ML
200437AC	G856-314-014-9-MLX
200439AC	G856-314-016-7-ML
200442AC	G856-314-016-8-ML
200443AC	G856-314-016-8-MLX
200444AC	G856-314-016-9-ML
200446AC	G856-314-018-8-F
200447AC	G856-314-018-8-ML
200450AC	G856-314-018-9-ML
200453AC	G856-314-021-9-ML
200454AC	G856-314-021-9-MLX
200462AC	G856L-314-014-10-ML
200464AC	G856L-314-016-10-ML
200467AC	G856L-314-018-10-ML
200485AC	G856XL-314-016-12-ML
200491AC	G858-314-012-8-ML
200502AC	G859-314-010-10-F
200503AC	G859-314-010-10-ML
200508AC	G859-314-014-10-F
200509AC	G859-314-014-10-ML
200525AC	G860-314-012-5-F
200527AC	G860-314-012-5-XF
200539AC	G862-314-010-8-F
200540AC	G862-314-010-8-ML
200543AC	G862-314-012-8-F
200544AC	G862-314-012-8-ML
200560AC	G863-314-012-10-ML
200563AC	G863-314-014-10-F
200565AC	G863-314-014-10-UF
200566AC	G863-314-014-10-XF
200568AC	G863-314-016-10-ML
200592AC	G877-314-012-6-ML
200616AC	G878-314-012-8-F
200617AC	G878-314-012-8-ML
200631AC	G878K-314-010-8-ML
200635AC	G878K-314-014-8-ML
200638AC	G878K-314-016-8-ML
200641AC	G878K-314-018-8-ML
200651AC	G879-314-012-10-ML
200653AC	G879-314-014-10-ML
200660AC	G879K-314-012-10-ML
200670AC	G879K-314-018-10-ML

FG Diamonds	
REF	**Beschreibung/*Description***
200679AC	G880-314-012-6-F
200680AC	G880-314-012-6-ML
200681AC	G880-314-012-6-UF
200682AC	G880-314-012-6-XF
200683AC	G880-314-014-6-ML
200684AC	G880-314-014-6-MLX
200685AC	G881-313-010-8-MLSS
200687AC	G881-313-014-8-MLSS
200689AC	G881-313-016-8-MLSS
200691AC	G881-314-010-8-ML
200695AC	G881-314-014-8-ML
200697AC	G881-314-016-8-F
200730AC	G886K-314-018-9.5-ML
200732AC	G889-314-009-3.5-F
200733AC	G889-314-009-3.5-ML
200797AC	G828-314-030-1-ML
200798AC	G828-314-022-1-ML
200800AC	G860-314-012-5-UF
200807AC	G881-313-016-8-FSS
205008AC	G836-314-014-6-FPX
205009AC	G836-314-016-6-FPX
205010AC	G836-314-018-6-FPX
205027AC	G848-314-016-10-FPX
205029AC	G848-314-018-10-FPX
205035AC	G850-314-016-10-FPX
205080AC	G878K-314-016-8-FPX
205082AC	G878K-314-018-8-FPX
205102AC	G886-314-014-10-FPX
205103AC	G886-314-016-10-FPX
205102AC	G886-314-014-10-FPX
251002AC	0941 FINISHING DIAMOND KIT
251003AC	0944 FP GOLD DIAMOND KIT
251007AC	0945 EASTMAN KIT
250101AC	188P POSTERIOR RESTO.&EQUILIBRATION KIT
250102AC	188A ANTERIOR RESTORATION KIT
200751AC	G909-314-040-1.5-ML
200752AC	G909-314-040-1.5-MLX
200756AC	G909-314-055-2-ML
200757AC	G909-314-055-2-MLX
200988AC	834-0.5ML DEPTH MARKER
200989AC	834-0.7ML DEPTH MARKER