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*:
Adresse/*Address*:

Coltène/Whaledent AG
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

Diatech Z-Rex

klassifiziert nach Anhang IX
der Richtlinie 93/42/EWG
classified according to annex IX
Directive 93/42/EEC

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 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* :

Diatech Z-Rex

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

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

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

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

Standard number and year:	SN EN ISO 6360-6
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
Standard name:	Dental rotary instruments – Diamond instruments – Part 1: Dimensions, requirements, marking and packaging

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

Anhang II / *Annex II* :

Diatech Z-Rex	
REF	**Beschreibung/*Description***
60022022	ZR379-314-023-5-M
60022023	ZR801-314-012-M
60022024	ZR801-314-014-M
60022025	ZR801-314-018-M
60022026	ZR850-314-016-10-M
60022027	ZR850-314-018-10-M
60022028	ZR856-314-018-8-M
60022029	ZR862-314-014-8-M
60022030	ZR863-314-014-10-M
60022031	ZR881-314-014-8-M
60022032	ZR881-314-016-8-C
60022152	DIATECH Zirconia Adjustment&Polishing Kit, 1 pc
60022153	DIATECH Z-Rex Intro Kit
60022160	DIATECH Z-Rex Intro Kit Refill
60022486	DIATECH Z-Rex Diamond Instruments G379-314-023-5-M, 5 pcs
60022487	DIATECH Z-Rex Diamond Instruments G801-314-012-M, 5 pcs
60022488	DIATECH Z-Rex Diamond Instruments G801-314-014-M, 5 pcs
60022489	DIATECH Z-Rex Diamond Instruments G801-314-018-M, 5 pcs
60022490	DIATECH Z-Rex Diamond Instruments G850-314-016-10-M, 5 pcs
60022491	DIATECH Z-Rex Diamond Instruments G850-314-018-10-M, 5 pcs
60022492	DIATECH Z-Rex Diamond Instruments G856-314-018-8-M, 5 pcs
60022493	DIATECH Z-Rex Diamond Instruments G862-314-014-8-M, 5 pcs
60022494	DIATECH Z-Rex Diamond Instruments G863-314-014-10-M, 5 pcs
60022495	DIATECH Z-Rex Diamond Instruments G881-314-014-8-M, 5 pcs
60022496	DIATECH Z-Rex Diamond Instruments G881-314-016-8-C, 5 pcs
60022570	DIATECH Z-Rex Intro Kit Refill China, 1 pc