COLTENE

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EC Declaration of Conformity of medical devices

According to annex II.3 of the Council Directive 93/42/EEC of June 14th, 1993

Coltène/Whaledent AG
Feldwiesenstr. 20
9450 Altstätten
Switzerland

declare under our sole responsibility that the following products:

Restoratives

- BRILLIANT EverGlow
- BRILLIANT EverGlow Flow
- BRILLIANT NG
- BRILLIANT Flow
- BRILLIANT Crios
- SYNERGY Nano Formula
- SYNERGY D6
- SYNERGY D6 Flow
- COMPONEER
- COMPONEER Brilliant
- DUO CEMENT plus
- SoloCem
- DuoCem
- ParaBond Adhesive
- ParaCore
- One Coat Bond
- One Coat Bond SL
- One Coat Self-Etching Bond
- One Coat 7.0
- ONE COAT 7 Universal
- A.R.T. Bond
- Margin Bond
- Paint on Color
- Etchant Gel

- Etchant Gel S
- Miris2
- Fill-Up!
- SwissTEC Composite
- SwissTEC SL Bond
- SwissTEC SL Etchant

Temporaries

- Coltosol F
- DuoTEMP
- Cool Temp Natural
- TempoSIL 2

Instruments

- DIATECH Diamond instruments
- DIATECH Carbide burs
- DIATECH Silicone polishers
- SwissFlex Discs

are classified according to annex IX of the Directive 93/42/EEC as class IIa, marked with CE 0123 (TÜV Süd Product Service, Munich) and meet the provisions of annex II.3.

This Declaration of Conformity is only valid in connection with the valid TÜV Product Service EC Certificate.

Altstätten, 28 July 2017

Coltène/Whaledent AG
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S. Benz

Silvan Benz
Director Quality Management and Regulatory Affairs