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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:

GMDN-Code: 38764

- BRILLIANT EverGlow
- BRILLIANT EverGlow Flow
- BRILLIANT NG
- BRILLIANT FLOW
- SYNERGY (Nano Formula)
- SYNERGY D6
- SYNERGY D6 Flow
- Fill-Up!
- Miris2

GMDN-Code: 35876

- ParaCore
- COMPONEER
- COMPONEER Brilliant
- BRILLIANT COMPONEER

GMDN-Code: 38766

- DUO CEMENT plus

GMDN-Code: 35870

- SoloCem
- DuoCem

GMDN-Code: 40592

- Paint on Color

COLTENE

GMDN-Code: 38649

- BRILLIANT Crios
- BRILLIANT Crios Disc

GMDN-Code: 34782

- ParaBond Adhesive
- One Coat Bond
- One Coat Bond SL
- One Coat Self-Etching Bond
- One Coat 7.0
- ONE COAT 7 Universal
- A.R.T. Bond

GMDN-Code: 36153

- Etchant Gel S

GMDN-Code: 16710

- Coltosol F
- DuoTEMP

GMDN-Code: 31783

- Cool Temp Natural
- TempoSIL 2

GMDN-Code not available

- DIATECH Diamond instruments	UMDNS-Code: 16-670
- DIATECH Z-Rex	UMDNS-Code: 16-670
- DIATECH Carbide burs	UMDNS-Code: 16-668
- DIATECH Silicone polishers	UMDNS-Code: 13-550

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, 24. April 2020

Dr. Daniel Meier
Manager Quality Assurance