Coltène/Whaledent AG
Feldwiesenstrasse 20
9450 Altstätten, Switzerland

T +41 71 757 53 00
F +41 71 757 53 01
www.coltene.com

EC Declaration of Conformity of medical devices

According to annex I and VII of the Council Directive 93/42/EEC of June 14th, 1993

Coltène/Whaledent AG
Feldwiesenstr. 20
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declare under our sole responsibility that the following products:

A-Silicones

- PRESIDENT (putty, putty soft, fast putty soft, light body, regular body, heavy body, System 360 heavy body)
- AFFINIS (putty soft, fast putty soft, putty super soft, System 360 putty, light body, fast light body, regular body, fast regular body, heavy body, fast heavy body, System 360 heavy body, MonoBody, System 360 MonoBody, PRECIOUS light body, PRECIOUS regular body)
- JET BLUE BITE (fast, superfast)
- JET BITE
- Magic FoamCord
- SwissTEC A-Silicone (light body, regular body, putty soft, fast putty soft)
- SwissTEC HydroXtreme (light body, regular body, heavy body, putty soft, putty soft fast, putty super soft)
- Adhesive
- Adhesive AC

C-Silicones

- Coltoflax
- Coltoflax mix
- Coltex (extrafine, extrafine mix, fine, medium, compact, mix)
- Rapid (Soft, Activator, Liner, Liner Activator)
- Speedex (putty, light body, medium, Universal Activator)
- PSI
- SwissTEC C-Silicone (light body, medium body, putty)
- Separator

Dental Instruments

- SwissFlex Strips

are classified according to annex IX of the Directive 93/42/EEC as class I marked with CE and meet the provisions of annex I and VII.

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

Altstätten, 08 March 2016

Coltène/Whaledent AG
Feldwiesenstrasse 20
9450 Altstätten/Switzerland

Silke Wallaschek
Head Regulatory Affairs