



FREE SALES CERTIFICATE

FOR THE HEALTH AUTHORITIES OF VIET NAM

Nr.: G-FSC-15-22518

valid until: 4 January 2019

The SWISS AGENCY FOR THERAPEUTIC PRODUCTS certifies herewith, that medical devices are regulated in Switzerland under the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products) of 15 December 2000 in force since 1 January 2002 and the Medical Devices Ordinance of 17 October 2001 in force since 1 January 2002.

The following medical device(s) meets (meet) the legal requirements set out in the Swiss Medical Devices Ordinance and which incorporates the Medical Devices Directives of the European Union:

DENTAL MATERIALS

- Impression Materials
 - Restoratives
 - Dental Instruments
 - SwissTEC brand
- according to the attached list (3 pages).

Therefore, the firm **Coltène/Whaledent AG, Feldwiesenstrasse 20, 9450 Altstätten, Switzerland,**

in conformity with the medical devices law of Switzerland is authorized to develop, manufacture and sell in Switzerland to physicians and hospitals for use on human beings, and to export into any country the CE marked medical device(s) above-mentioned.

This certificate is valid until 4 January 2019

Bern, 5 January 2016

Swiss Agency for Therapeutic Products
Medical Devices Division

CP



Claude-Philippe Petitpierre, Master of Law

Fee: CHF 300.00

gfsc_lm_cott_15-22518



No. 000241

Seen for legalization of the signature of
C.P. Petitpierre/Swissmedic/Swiss Agency
for Therapeutic Products

Berne, 07. JAN. 2016

SWISS FEDERAL CHANCELLERY

Yvonne Agosti



Tax CHF 20.-



ĐẠI SỨ QUÁN VIỆT NAM TẠI THỤY SỸ
EMBASSY OF VIETNAM IN SWITZERLAND

CHỨNG NHẬN / HỢP PHÁP HOÁ LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia:
Country

Việt Nam

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà): YVONNE AGOSTI ký
has been signed by

3. với chức danh
acting in the capacity of

4. và con dấu của Văn phòng Liên Bang
bears the seal/stamp of

được chứng nhận / hợp pháp hoá lãnh sự
Certified

5. tại: BERN
at

6. ngày 12 / 01/2016
the

7. Cơ quan cấp: Embassy of Vietnam in Switzerland
by

8. Số: 17 /CNLS/HPHLS
N^o

Ký tên và đóng dấu
Signature and seal/stamp

TL. ĐẠI SỨ
THAM TÂN

Nghiem Van Long



Dental Materials

1. Impression materials

A-Silicones

- 1 - President putty
- 2 - President putty soft
- 3 - President fast putty soft
- 4 - President light body
- 5 - President Jet light body
- 6 - President regular body
- 7 - President Jet regular body
- 8 - President heavy body
- 9 - President System 360 heavy body
- 10 - AFFINIS putty soft
- 11 - AFFINIS fast putty soft
- 12 - AFFINIS putty super soft
- 13 - AFFINIS System 360 putty
- 14 - AFFINIS light body
- 15 - AFFINIS fast light body
- 16 - AFFINIS regular body
- 17 - AFFINIS fast regular body
- 18 - AFFINIS heavy body
- 19 - AFFINIS fast heavy body
- 20 - AFFINIS System 360 heavy body
- 21 - AFFINIS MonoBody
- 22 - AFFINIS System 360 MonoBody
- 23 - AFFINIS PRECIOUS light body
- 24 - AFFINIS PRECIOUS regular body
- JET Blue Bite fast
- Jet Blue Bite superfast
- Jet Bite
- 25 - Magic FoamCord
- Adhesive
- Adhesive AC

C-Silicones

- 26 - Coltoflax
- 27 - Coltoflax mix
- Coltex extrafine
- Coltex extrafine mix
- Coltex fine
- Coltex medium
- Coltex compact
- Coltex mix
- Rapid
- Rapid Soft
- Rapid Activator
- Rapid Liner

- Rapid Liner Activator
- Speedex putty
- Speedex light body
- Speedex medium
- Speedex Universal Activator
- PSI

2. Restoratives

- Brilliant Dentin
- Brilliant Enamel
- Brilliant Incisal
- Brilliant EverGlow
- Brilliant NG
- Brilliant Flow
- Synergy Duo Shade
- 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 Colors
- Etchant Gel
- Etchant Gel S
- Separator
- Miris2
- Fill-Up!

2.1 Temporaries

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

3. Dental Instruments

3.1. Diatech brand

- 28 Diamond instruments
- 29 Carbide burs
- 30 Silicone polishers
- 31 Polishing brushes
- 32 SwissFlex Discs
- 33 SwissFlex Strips
- 34 DIAStrip

4. SwissTEC brand

4.1 Impression material

- 35 - SwissTEC HydroXtreme light body
- 36 - SwissTEC HydroXtreme regular body
- 37 - SwissTEC HydroXtreme heavy body
- 38 - SwissTEC HydroXtreme putty soft
- 39 - SwissTEC HydroXtreme putty soft fast
- 40 - SwissTEC HydroXtreme putty super soft
- 41 - SwissTEC A-Silicone light body
- 42 - SwissTEC A-Silicone regular body
- 43 - SwissTEC A-Silicone putty soft
- 44 - SwissTEC A-Silicone fast putty soft
- 45 - SwissTEC C-Silicone light body
- 46 - SwissTEC C-Silicone medium body
- 47 - SwissTEC C-Silicone putty

4.2 Restoratives

- SwissTEC Composite
- SwissTEC SL Bond
- SwissTEC SL Etchant