

**DECLARATION OF CONFORMITY  
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993  
CONCERNING MEDICAL DEVICES**



**Manufacturer:** Guangzhou Fengdan Medical Equipment Co., Ltd.

**Medical Device:** Integral dental unit (except for dental turbine handpiece, toothdrill and the suction head)

**Model:** QL2028, QL2028I, QL2028II, QL2028III, QL2028IV, BZ636, BZ637, BZ638, BZ639

**Classification - Annex IX:** Class IIa, Rule 5, 9

**Conformity assessment Route:** Annex V

**We, Guangzhou Fengdan Medical Equipment Co., Ltd.,**

**Office Address:** No .286, Caixin Road, Lanhe Town, Nansha District, Guangzhou City, Guangdong Province 511480, P.R. China. All supporting documentation is retained at the premises of the manufacturer.

**European representative:** S . C. NASTIMED SERV S . R. L

Str. m. Eminescu, nr 1, Cluj Napoca, Romania

**EC REP**

declare at our sole responsibility that products Integral Dental Unit, model: QL2028, QL2028I, QL2028II, QL2028III, QL2028IV, BZ636 and falling class IIa, rule 5, 9 comply with requirements of directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 march 2010, the amendments by council directive 2007/47/EEC.

**NOTIFIED BODY:**

SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium

Country: Belgium

Website: www.sgs.com

**CE** 1639, has performed ANNEX V and issued the certificate.

**(EC) Certificate(s):** CN19/41121

**Start of CE-marking:** 16 March 2012

**Date of declaration:** 2022. 12.30

**Place, Date of Declaration:** China Guangdong Province 2022.12.30

**Signature:**

  
Name: Calvin Chen

Position: responsible senior executive of manufacturer