



(GALSAN-DONG)348,SEONGSE-RO, DALSEO-GU, DAEGU, KOREA

T.:++82-53-582-9000 / F.:++82-53-581-9003

## EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Model Name :

**Dental contra angle handpiece : SP-RA16**

**Dental controller for contra angle handpiece : ENDO A CLASS**

Classification :

**Class IIa (Annex IX Rule 9, Council Directive 93/42/EEC as amended by Directive 2007/47/EC).**

Conformity Assessment Route :

**Annex II, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC.**

Notified Body :

**SGS UK Ltd.**

**nit 202B, World Parkway Weston-Super-Mare Somerset**

**BS 22 OWA United Kingdom**

Standards applied :

**2003, EN ISO14971:2012, ISO3964:1982, ISO7494-1:2004, ISO7785-2:1995,  
ISO11498:1997, ISO6507-2:2005, ISO1797-1:1992, ISO1797-2:1992,  
ISO9687:1993, ISO13402:1995, ISO17665-1:2006, ISO14155-1:2003,  
EN1041:2008, ISO15223-1:2012, EN60601-1:2006, EN60601-1-2:2007,  
EN60601-1-6:2010, EN62304:2006**

Manufacturers Registered Name : **Saeyang Microtech Co.,Ltd.**

EC Representative : **MARATHON ITALIA SRL. VIA NUOVA SAN ROCCO, 62, 80131. NAPOLI, ITALY**



Signature :

Date : Dec. 2, 2015.

Jung Pil Shin / CEO