



EC Declaration of Conformity

In accordance with ISO 17050-1:2004

Manufacturer : : Surgident Co.

#210, Woolim Lion's Vally, 27, Dunchon-daero457beon-gil, Jungwon-gu,
Seongnam-si, Gyeonggi-do, Korea

European representative : DongBang AcuPrime

1 The Forrest Units Hennock Road East
Exeter, EX2 8RU, UK

Common name : Dental surgical instrument(Re-usable and non-powered)

Model: SD-TORQUE, BONE MILL, TOCA KIT, AQUA TOCA-KIT, WRS-KIT, NLBC-KIT, TOLA-KIT, EASY SINUS KIT, BONE MULTI SYSTEM, BONE EXPANDER KIT, BONE SPREADING KIT, RIDGE SPLIT SET, OSTEOTOME S-SET, OSTEOTOME R-SET, TOP SYSTEM, TRIMMER KIT, P.R.F SYSTEM, BASIC KIT, SD REAMER SET, STOP DRILL KIT, SINGLE OUT, MP20, IPD KIT, TOLA KIT II, EASY BONE EXPANDER KIT

Classification : Class I by Rule 6 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC

Conformity Assessment Route : Annex VII, MDD 93/42/EEC as amended by 2007/47/EC

We hereby declare that the complies with the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) using Annex VII as the conformity assessment procedure. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied :

ISO 13485[2003] Medical devices – Quality management system
ISO 14971[2007] Medical devices-Application of risk management to medical devices
EN 980 [2008] Graphical symbols for use in the labeling of medical devices
EN 1041 [2008] Information supplied by the manufacturer with medical devices



Start of CE-marking : 2011.Nov.24

**Place, Date of issue : #210, Woolim Lion's Valley, 27,
Dunchon-daero457beon-gil, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Korea**

Signature :

**President
on behalf of Surgident**