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**Manufacturer :** MegaGen Implant Co., Ltd.

**Address :** 377-2, Gyochon-ri, Jain-myeon,  
Gyeongsan-si, Gyeongbuk, Korea

**Product :** **Dental Gauge**  
of Dental Implant system is intended to measure the depth of the gingival  
or bone or the distance of the next position where the clinician has to  
insert dental implant. The instrument may re-use if cleaned and sterilized

**GMDN Code :** 31846

**Classification (MDD Annex IX) :** Im, Rule 6

We herewith declare under our sole responsibility that the above mentioned product meets all the essential requirements of the following EC Council Directive and the provisions of the following Standards. All supporting documentation is retained under the promises of the manufacturer and the notified body.

#### DIRECTIVES

##### General applicable directive:

Council Directive 93/42/EEC as amended by 2007/47/EC of 5 September 2007 concerning medical devices(MDD 2007/47/EC)

##### Standards :

##### Standards applicable to this product are :

EN ISO 13485:2012, EN ISO 14971:2012, EN 1639:2009  
EN ISO 17665-1:2006, EN 980:2008  
EN 1041:2008

**Notified body :** Det Norske Veritas Certification AS, Identification No.0434  
Veritasveien 1, 1322 Høvik, Norway

**Conformity Assessment Route :** MDD 2007/47/EC Annex II excluding section 4

This declaration is valid for the above mentioned CE-marked products after the signature date below and until the expiration of the EC-Certificate No. 71220-2010-CE-KOR-NA Rev 9.0 issued by Det Norske Veritas Certification AS(Valid until: 08 March 2016).

**Place, Valid from (date) :** September 12, 2013

**Signature :** 

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Name : Kwang-Bum Park  
Position : CEO / President  
One behalf of MegaGen Implant Co., Ltd

**EC Authorized Representative**  
ImplaMedica Ltd.  
Fabijoniskiu 39-45, Vilnius LT-07120  
Lithuania