EC Declaration of Conformity

Manufacturer : MegaGen Implant Co., Ltd.

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

Product : **AnyOne® Internal Fixtures**
of Dental Implant system is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function.

GMDN Code : 55849

Classification (MDD Annex IX) : IIb, Rule 8

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 1642:2011,
EN ISO 10993-1:2009, ISO 14801:2007,
EN 556-1:2001, EN ISO 11137-1:2006, EN ISO 11137-2:2012, EN ISO 11737-1:2006,
EN ISO 11607-1:2009, EN ISO 11607-2:2006, BS EN ISO 15223-1:2012, 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 11.0 issued by Det Norske Veritas Certification AS(Valid until: 08 March 2016).

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

Signature : Kwang Bum PARK

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