EC Declaration of Conformity

Issue No. : DoC - 006
Version : 01

Manufacturer : MegaGen Implant Co., Ltd.

Address : 472, Hanjanggun-ro, Jain-myeon, Gyeongsan-si, Gyeongsangbuk-do, Korea, Republic of, 712-852

Product : **Abutments & Accessories for AnyOne® Internal Implant**
of Dental Implant system is intended to be placed on the fixture and connected to the fixture with screw, such as artificial teeth, and to restore a patient's chewing function

GMDN Code : 44879

Classification (MDD Annex IX) : IIb, IIa, 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 t0he 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 10993-1:2009, EN ISO 11137-1:2006, EN ISO 11137-2:2012
EN ISO 17665-1:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009
BS EN ISO 15223-1:2012, EN ISO 11607-1:2009, 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 12.0 issued by Det Norske Veritas Certification AS(Valid until: 08 March 2016).

Place, Valid from (date) : March 24, 2014

Signature : Kwang Bum PARK

Name : Kwang-Bum Park

Position : CEO / President
One behalf of MegaGen Implant Co., Ltd.

EC Authorized representative
ImplaMedica Ltd.
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