EC Declaration of Conformity

Issue No. : DoC - 003
Version : 01

Manufacturer : MegaGen Implant Co., Ltd.

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

Product : **Surgical Instruments**
is intended for making a hole on the bone and for expanding the hole made to insert fixture.

GMDN Code : 45714

Classification (MDD Annex IX) : IIa, 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 ISO 11737-1:2006
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 V

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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Lithuania