EC Declaration of Conformity

Issue No. : DoC - 018
Version : 01

Manufacturer : MegaGen Implant Co., Ltd.

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

Product : **MEGA SIL**
A dental impression material designed to reproduce the structure of a patient's teeth and gums, or other oral anatomy, after being placed on an impression tray and inserted into the mouth.

GMDN Code : -

Classification (MDD Annex IX) : I, Rule 5

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 9.0 issued by Det Norske Veritas Certification AS(Valid until: 08 March 2016).

Place, Valid from (date) : Oct 15, 2013

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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