EC Declaration of Conformity

MegaGen Implant Co., Ltd.
377-2, Gyochon-ri, Jain-myeon,
Gyeongsan-si, Gyeongbuk, Korea

declare that the medical devices described hereafter

The **Dental Implant Superstructure** 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
(refer to the Attachment 1 for product list details)

and has been classified as **Class IIa** (Annex IX Rule 5) and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC

and are in conformity with the following harmonized standards
EN ISO 13485:2003, EN ISO 14971:2009, EN 1642:2009,
EN ISO 10993-1:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006,
EN ISO 11137-1:2006, EN ISO 17665-1:2006, EN ISO 11737-1:2006,
EN 980:2008, EN 1041:2008
(refer to the Attachment 2 for standards details)

and are subject to the procedure set out in **Annex II excluding section 4** of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body 0434, Det Norske Veritas Certification AS, Veritas veien 1, 1322 Høvik, Norway

March 12, 2012

Il Kim
Quality Director
On behalf of MegaGen Implant Co., Ltd.

EC Authorised representative
ImplaMedica., Ltd.
Fabijoniskiu 39-45, Vilnius LT-07120,
Lithuania

Attachment 1 – Product list

Certificate No.: 71220-2010-CE-KOR-NA Rev 8.0

Manufacturer: MegaGen Implant Co., Ltd.

Product Description	Product Name
ExFeel™ External Implant System	Fixture Mount & Screw Cover Screw Healing Abutment Esthetic Healing Abutment EZ Post Angled Abutment Abutment Screw Temporary Abutment Impression Coping & Guide Pin Lab Analog Gold Abutment Plastic Abutment Gold Screw Regular Abutment Wide Abutment Ball Abutment
ExFeel™ Internal Implant System	Cover Screw & Closing Screw Healing Abutment Multi Post & Multi Post Screw Multi Post Cap Angled Abutment Abutment Screw Impression Coping & Guide Pin Lab Analog Gold Abutment Solid Abutment Solid Cap Solid Post Abutment Solid Post Cap Impression Cap Positioning Cylinder

	Solid Analog Shoulder Analog & Shoulder Analog Pin Octa Abutment Plastic Abutment Octa Healing Cap Ball Abutment
Intermezzo™ Implant System	Lab Analog Solid Cap Snap Impression Coping
EZ Plus™ External Implant System	Multi Mount & Multi Mount Screw Multi Mount Sealing Screw Ball Abutment
EZ Plus™ Internal Implant System	Multi Post Multi Post Screw Cover Screw Healing Abutment Abutment Screw EZ Post Solid Abutment Angled Abutment Impression Coping & Guide Pin Lab Analog Comfort Cap Snap Impression Coping Burn-out Cylinder Gold Abutment Temporary Abutment Octa Abutment Ball Abutment
Rescue™ External Implant System	Fixture Mount & Mount Screw Cover Screw Healing Abutment EZ Post Angled Abutment Temporary Abutment Abutment Screw Impression Coping & Guide Pin Lab Analog

	Gold Abutment Plastic Abutment Wide Abutment Wide Abutment Screw Healing Cap Ball Abutment
Rescue™ Internal Implant System	Cover Screw Healing Abutment EZ Post Solid Abutment Temporary Abutment Abutment Screw Impression Coping & Guide Pin Snap Impression Coping Lab Analog Burn-out Cylinder Comfort Cap Gold Abutment Ball Abutment
AnyRidge™ Internal Implant System	Cover Screw Healing Abutment Impression Coping Guide Pin Lab Analog Temporary Abutment Gold Abutment EZ Post Extra EZ Post Angled Abutment Solid Abutment Milling Abutment Octa Abutment Ball Abutment Multi Post Screw Snap Impression Coping Comfort Cap Burn out Cylinder

Attachment 2 – Applied Standards

General Requirements

- EN ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971:2009, Medical devices - Application of risk management to medical devices
- EN 1642:2009, Dentistry. Medical devices for dentistry. Dental implants
- ISO 15225:2010, Medical devices -- Quality management -- Medical device nomenclature data structure

Physical and mechanical Safety and effectiveness

- ASTM F67-06, Standard Specification for Unalloyed Titanium, for Surgical Implant Application (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
- ASTM F136 - 08e1 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F899 – 11, Standard Specification for Wrought Stainless Steels for Surgical Instruments

Biological Safety and effectiveness

- EN ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management
- ASTM F136-11, Standard Specification for Wrought titanium - 6Aluminum – 4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Application (UNS R56401)
- ASTM F899–11, Standard Specification for Wrought Stainless Steels for Surgical Instruments

Packaging

- EN ISO 11607-1:2009, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F88 / F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials

Labelling

- EN 980:2008, Symbols for use in the labelling of medical devices
- EN 1041:2008, Information supplied by the manufacturer of medical devices

Sterilization

- EN 556-1:2001, Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
- EN ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11137-2:2007, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- EN ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

- ISO/TS 17665-2:2009, Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1
- EN ISO 11737-1:2006, Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- EN ISO 11737-2:2009, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Clinical evaluation

- MEDDEV. 2.7.1 Rev.3, Clinical evaluation: A guide for manufacturers and notified bodies