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

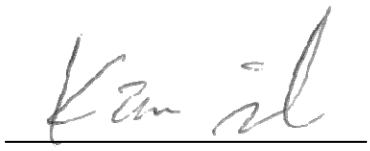
The **Dental Implant** of Dental implant system are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. (refer to the Attachment 1 for Product list details)

and have been classified as **Class IIb** (Annex IX Rule 8) 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, ISO 14801:2007, EN 556-1:2001,
EN ISO 11137-1:2006, EN ISO 11137-2:2007, EN ISO 11737-1:2006,
EN ISO 11607-1:2009, EN ISO 11607-2:2006, 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 Name	Model Name
ExFeel™ External Implant System	• ExFeel™ External Fixtures Φ3.30mm: SDR3308, SDR3310, SDR3311, SDR3313, SDR3315, SDR3318 Φ3.75mm: RDR3708, RDR3710, RDR3711, RDR3713, RDR3715, RDR3718 Φ4.00mm: RDR4008, RDR4010, RDR4011, RDR4013, RDR4015, RDR4018 Φ4.50mm: RDR4508, RDR4510, RDR4511, RDR4513, RDR4515, RDR4518 Φ5.00mm: TWDR5008, TWDR5010, TWDR5011, TWDR5013, TWDR5015, TWDR5018
ExFeel™ Internal Implant System	• ExFeel™ Internal Fixtures: Straight Body Type Φ3.50mm: ISDB3507, ISDB3508, ISDB3510, ISDB3511, ISDB3513 Φ4.10mm: ISDB4107, ISDB4108, ISDB4110, ISDB4111, ISBD4113 ISDB4107E, ISDB4108E, ISDB4110E, ISDB4111E, ISBD4113E Φ4.80mm: ISDB4807, ISDB4808, ISDB4810, ISDB4811, ISDB4813 ISDB4807E, ISDB4808E, ISDB4810E, ISDB4811E, ISDB4813E Φ5.50mm: ISDB5507, ISDB5508, ISDB5510, ISDB5511, ISDB5513, ISDB5507E, ISDB5508E, ISDB5510E, ISDB5511E, ISDB5513E • ExFeel™ Internal Fitxures: Tapered Body Type Φ3.50mm: ITDB3507, ITDB3508, ITDB3510, ITDB3511, ITDB3513 Φ4.10mm: ITDB4107, ITDB4108, ITDB4110, ITDB4111, ITDB4113 ITDB4107E, ITDB4108E, ITDB4110E, ITDB4111E, ITDB4113E Φ4.80mm: ITDB4807, ITDB4808, ITDB4810, ITDB4811, ITDB4813 ITDB4807E, ITDB4808E, ITDB4810E, ITDB4811E, ITDB4813E

	Φ5.50mm: ITDB5507, ITDB5508, ITDB5510, ITDB5511, ITDB5513,ITDB5507E, ITDB5508E, ITDB5510E, ITDB5511E, ITDB5513E
Intermezzo™ Implant System	• Intermezzo™ Fixtures Φ1.60mm: IMTI1610, IMTI1611, IMTI1613, IMTI1615 Φ2.00mm: IMTI2010, IMTI2011, IMTI2013, IMTI2015 Φ2.50mm: IMTI2510, IMTI2511, IMTI2513, IMTI2515 Φ3.10mm: IMTI3110, IMTI3111, IMTI3113, IMTI3115
EZ Plus™ External Implant System	• EZ Plus™ External Fixtures Φ3.30mm: EZES3307,EZES3308, EZES3310, EZES3311, EZES3313, EZES3315, EZES3318 Φ4.00mm: EZER4007,EZER4008, EZER4010, EZER4011, EZER4013, EZER4015, EZER4018 Φ5.00mm: EZEW5007, EZEW5008, EZEW5010, EZEW5011, EZEW5013, EZEW5015, EZEW5018
EZ Plus™ Internal Implant System	• EZ Plus™ Internal Fixtures Φ3.30mm: EZIS3307,EZIS3308, EZIS3310, EZIS3311, EZIS3313, EZIS3315, EZIS3318 Φ4.00mm: EZIR4007,EZIR4008, EZIR4010, EZIR4011, EZIR4013, EZIR4015, EZIR4018 Φ4.10mm: EZIR4008, EZIR4010, EZIR4011, EZIR4013, EZIR4015, EZIR401 Φ4.50mm: EZIR4507,EZIR4508, EZIR4510, EZIR4511, EZIR4513, EZIR4515, EZIR4518 Φ5.00mm: EZIW5007,EZIW5008, EZIW5010, EZIW5011, EZIW5013, EZIW5015, ZIW5018
Rescue™ External Implant System	• Rescue™ External Fixtures Φ6.0mm: RSWR6005, RSWR6006, RSWR6007, RSWR6008, RSWR6010, RSWR6011, RSWR6013 Φ6.5mm: RSWR6505, RSWR6506, RSWR6507, RSWR6508, RSWR6510, RSWR6511, RSWR6513 Φ7.0mm: RSWR7005, RSWR7006, RSWR7007, RSWR7008, RSWR7010, RSWR7011, RSWR7013 Φ7.5mm: RSWR7505, RSWR7506, RSWR7507, RSWR7508, RSWR7510, RSWR7511, RSWR7513 Φ8.0mm: RSWR8005, RSWR8006, RSWR8007, RSWR8008, RSWR8010, RSWR8011, RSWR8013
Rescue™ Internal Implant System	• Rescue™ Internal Fixtures

	Φ6.0mm: RSWIR6005, RSWIR6006, RSWIR6007, RSWIR6008, RSWIR6010, RSWIR6011, RSWIR6013 Φ6.5mm: RSWIR6505, RSWIR6506, RSWIR6507, RSWIR6508, RSWIR6510, RSWIR6511, RSWIR6513 Φ7.0mm: RSWIR7005, RSWIR7006, RSWIR7007, RSWIR7008, RSWIR7010, RSWIR7011, RSWIR7013 Φ7.5mm: RSWIR7505, RSWIR7506, RSWIR7507, RSWIR7508, RSWIR7510, RSWIR7511, RSWIR7513 Φ8.0mm: RSWIR8005, RSWIR8006, RSWIR8007, RSWIR8008, RSWIR8010, RSWIR8011, RSWIR8013
AnyRidge™ Internal Implant System	• AnyRidge™ Internal Fixtures Ø3.5mm: FANIHR3507, FANIHR3508, FANIHR3510, FANIHR3511, FANIHR3513, FANIHR3515, FANIHR3518 Ø4.0mm: FANIHR4007, FANIHR4008, FANIHR4010, FANIHR4011, FANIHR4013, FANIHR4015, FANIHR4018 Ø4.5mm: FANIHR4507, FANIHR4508, FANIHR4510, FANIHR4511, FANIHR4513, FANIHR4515, FANIHR4518 Ø5.0mm: FANIHR5007, FANIHR5008, FANIHR5010, FANIHR5011, FANIHR5013, FANIHR5015, FANIHR5018 Ø5.5mm: FANIHR5507, FANIHR5508, FANIHR5510, FANIHR5511, FANIHR5513, FANIHR5515, FANIHR5518 Ø6.0mm: FALIHR6007, FALIHR6008, FALIHR6010, FALIHR6011, FALIHR6013, FALIHR6015 Ø6.5mm: FALIHR6507, FALIHR6508, FALIHR6510, FALIHR6511, FALIHR6513, FALIHR6515 Ø7.0mm: FALIHR7007, FALIHR7008, FALIHR7010, FALIHR7011, FALIHR7013, FALIHR7015 Ø7.5mm: FALIHR7507, FALIHR7508, FALIHR7510, FALIHR7511, FALIHR7513, FALIHR7515 Ø8.0mm: FALIHR8007, FALIHR8008, FALIHR8010, FALIHR8011, FALIHR8013, FALIHR8015

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

- ISO 14801:2007, Dentistry - Implants - Dynamic fatigue test for endosseous dental implants

Biological Safety and effectiveness

- ASTM F67-06, Standard Specification for Unalloyed Titanium, for Surgical Implant Application (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
- EN ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing
- EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-6:2009, Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
- ISO 10993-10:2009, Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization
- EN ISO 10993-11:2009, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
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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
- ASTM F1980-07(2011); Standard Guide for Accelerated Aging of Sterile Barrier Systems for 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 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

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

Clinical evaluation

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