DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 71220-2010-CE-KOR-NA Rev. 6.0
This Certificate consists of **7** pages

This is to certify that the Quality Management System of

MegaGen Implant Co., Ltd.

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

for design, production and final product inspection/testing of

Dental Implant Systems

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 08 September 2011

This Certificate is valid until:
08 March 2016

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

NORWEGIAN ACCREDITATION
PROD 002

CE

Cecilie Gudesen Torp
Certification Manager

Notified Body No.:
0434

Angela Lanna
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original Certificate (2006-OSL-MDD-0074)	2006-03-08
1.0	New models included	2007-04-11
2.0	Change in manufacturer's name and new certificate number	2008-10-16
3.0	Specification of the model types are added the certificate	2009-01-21
4.0	Specification of the model types are added to the certificate and changed company name of the EC Rep	2010-02-03
5.0	Recertification – former certificate no.: 38456-2008-CE-NOR, New models added (in bold)	2011-02-14
6.0	**New product added (in bold)**	**2011-09-08**

Products covered by this Certificate

Product Description	Product Name	Class
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	IIb
ExFeel™ Internal Implant System	• ExFeel™ Internal Fixtures: Straight Body Type • Φ3.50mm: ISDB3507, ISDB3508, ISDB3510, ISDB3511, ISDB3513 • Φ4.10mm: ISDB4107, ISDB4108, ISDB4110, ISDB4111, ISBD4113 • Φ4.80mm: ISDB4807, ISDB4808, ISDB4810, ISDB4811, ISDB4813 • ExFeel™ Internal Fitxures: Tapered Body Type • Φ3.50mm: ITDB3507, ITDB3508, ITDB3510,	IIb

	ITDB3511, ITDB3513 • Φ4.10mm: ITDB4107, ITDB4108, ITDB4110, ITDB4111, ITDB4113 • Φ4.80mm: ITDB4807, ITDB4808, ITDB4810, ITDB4811, ITDB4813	
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	IIb
EZ Plus™ External Implant System	• EZ Plus™ External Fixtures • Φ3.30mm: EZES3308, EZES3310, EZES3311, EZES3313, EZES3315, EZES3318 • Φ4.00mm: EZER4008, EZER4010, EZER4011, EZER4013, EZER4015, EZER4018 • Φ5.00mm: EZEW5008, EZEW5010, EZEW5011, EZEW5013, EZEW5015, EZEW5018	IIb
EZ Plus™ Internal Implant System	• EZ Plus™ Internal Fixtures • Φ3.30mm: EZIS3308, EZIS3310, EZIS3311, EZIS3313, EZIS3315, EZIS3318 • Φ4.00mm: EZIR4008, EZIR4010, EZIR4011, EZIR4013, EZIR4015, EZIR4018 • Φ4.50mm: EZIR4508, EZIR4510, EZIR4511, EZIR4513, EZIR4515, EZIR4518 • Φ5.00mm: EZIW5008, EZIW5010, EZIW5011, EZIW5013, EZIW5015, ZIW5018	IIb
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	IIb
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**	**IIb**
ExFeel™ External Implant System	• Fixture Mount & Screw • Cover Screw • Healing Abutment • Esthetic Healing Abutment • EZ Post	IIa

	• Angled Abutment • Abutment Screw • Temporary Abutment • Impression Coping & Guide Pin • Lab Analog • Gold Abutment • Plastic Abutment • Gold Screw • Regular Abutment • Wide 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	IIa
Intermezzo™ Implant System	• Lab Analog • Solid Cap • Snap Impression Coping	IIa
EZ Plus™ External Implant System	• Multi Mount & Multi Mount Screw • Multi Mount Sealing Screw	IIa
EZ Plus™ Internal Implant System	• Multi Post • Multi Post Screw • Cover Screw • Healing Abutment • Abutment Screw • EZ Post • Solid Abutment	IIa

	• Angled Abutment • Impression Coping & Guide Pin • Lab Analog • Comfort Cap • Snap Impression Coping • Burn-out Cylinder • Gold Abutment • Temporary Abutment • Octa 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	IIa
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	IIa
AnyRidge™ Internal Implant System	• **Cover Screw** • **Healing Abutment** • **Impression Coping** • **Guide Pin** • **Lab Analog** • **Temporary Abutment**	**IIa**

	• **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**	

Sites covered by this certificate

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

EU Representative

UAB ImplaMedica, Fabijoniskiu 39-45, Vilnius LT-07120, Lithuania

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE