DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 71220-2010-CE-KOR-NA Rev.11.0

This Certificate consists of 5 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 and Dental Surgical Instruments

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, 21 January 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Jenny Helen Nytun
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
08 March 2016

Aud Løken Eiklid
Technical Reviewer

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

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.
If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.

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	2011-02-14
6.0	New product added	2011-09-08
7.0	Certificate integration (certificate no; 2239-2007-CE-NOR & 2243-2007-CE-NOR)	2011-10-05
8.0	New models added	2012-05-21
9.0	New models added and modify the content of certificate	2012-09-27
10.0	New models added	2013-07-15
11.0	**New models added (in bold) and changed classification of abutments**	**2014-01-21**

Products covered by this Certificate

Product Description	Product Name	Class
Dental Implants	• ExFeel® External Fixtures • ExFeel® Internal Fixtures • Intermezzo® Fixtures • EZ Plus® External Fixtures • EZ Plus® Internal Fixtures • Rescue® External Fixtures • Rescue® Internal Fixtures • AnyRidge® Internal Fixtures • XPEED® AnyRidge® Internal Fixtures • AnyOne® Internal Fixtures • MiNi® Internal Fixtures • **OnePiece® Fixture**	IIb

Palatal Denture Stabilizer	• Palatal Denture Stabilizer®	IIb
Prosthetic Systems for Dental Implant	• Abutments for ExFeel® External Implant • Abutments for ExFeel® Internal Implant • Abutments for Intermezzo® Implant • Abutments for EZ Plus® External Implant • Abutments for EZ Plus® Internal Implant • Abutments for Rescue® External Implant • Abutments for Rescue® Internal Implant • Abutments for AnyRidge® Internal Implant • Abutments for AnyOne® Internal Implant • Abutments for MiNi® Internal Implant • Customized Abutment	**IIb**
	• Accessories for ExFeel® External Implant • Accessories for ExFeel® Internal Implant • Accessories for Intermezzo® Implant • Accessories for EZ Plus® External Implant • Accessories for EZ Plus® Internal Implant • Accessories for Rescue® External Implant • Accessories for Rescue® Internal Implant • Accessories for AnyRidge® Internal Implant • Accessories for AnyOne® Internal Implant • Accessories for MiNi® Internal Implant • **Accessories for OnePiece® Implant** • **Dental Attachment**	IIa
Accessory for dental implant surgery (stabilize and support of bone graft)	• i-Gen®	IIa
Surgical instrument	• Lance Drill • Lindermann Drill • Tissue Punch • Twist Drill • Straight Drill • Stopper Drill • Intermezzo Drill • Pilot Drill • Shaping Drill • Tap • Countersink • Bottom Drill	IIa

	• Coronal Drill • Cortical Bone Drill • Point Trephine Bur • ASBE Trephine • Trephine Bur • Bone Profiler • Diamond Drill • Reamer Drill • Bone Expander • Surgical Instrument Kit Case • Dense Drill • Cortical Drill Tip • Initial Guide Drill • Express Bur • Auto-Max • Initial Drill • Anchor Pin • **EZ Draw**	
Harvest device for Soft Tissue	• Soft Tissue Harvester	IIa
Surgical instrument with measuring function	• Depth Gauge • Sinus Lift Instrument • Restome • Megatome	Im

Sites covered by this certificate

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

EU Representative

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