



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 71220-2010-CE-KOR-NA Rev.13.0

This Certificate consists of 6 pages

This is to certify that the Quality Management System of

MegaGen Implant Co., Ltd.

Korea, Republic of

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, 07 March 2016

This Certificate is valid until:

08 March 2021

For DNV GL BUSINESS ASSURANCE
NORWAY AS

Alexey Shiryaev
Certification Manager



Notified Body No.:
0434

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.





Cert. No.: 71220-2010-CE-KOR-NA
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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 and changed classification of abutments	2014-01-21
12.0	New models added and change in model name Address changed; based on street names	2014-12-02
13.0	Recertification	2016-03-07

Products covered by this Certificate

Product Description	Product Name	Class
Dental Implants	<ul style="list-style-type: none"> • ExFeel® External Fixtures • ExFeel® Internal Fixtures • Intermezzo® Fixtures • EZ Plus® External Fixtures • EZ Plus® Internal Fixtures • Rescue® External Fixtures • Rescue® Internal Fixtures 	IIb





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	<ul style="list-style-type: none"> • AnyRidge® Internal Fixtures • XPEED® AnyRidge® Internal Fixtures • AnyOne® External Fixtures • AnyOne® Internal Fixtures • MiNi® Internal Fixtures • MiNi® Post Fixtures • MiNi® Overdenture Fixtures 	
Palatal Denture Stabilizer	<ul style="list-style-type: none"> • Palatal Denture Stabilizer® 	IIb
Prosthetic Systems for Dental Implant	<ul style="list-style-type: none"> • EZ Post Abutment • EZ Post Cylinder • Extra EZ Post Abutment • Angled Abutment • Gold Abutment • Gold Cylinder • Regular Abutment • Wide Abutment • Multi Post • Solid Abutment • Octa Abutment • Milling Abutment • Ball Abutment • Zirconia Abutment • CCM Abutment • CCM Cylinder • Flat Abutment • Flat CCM Cylinder • Flat Gold Cylinder • Flat EZ Post Cylinder • ZrGEN Abutment • TiGEN Abutment • Multi-unit Abutment • Multi-unit Angled Abutment • Multi-unit Abutment Package • Meg-Rhein Abutment • Meg-Rhein Overdenture System 	IIb
	<ul style="list-style-type: none"> • Temporary Abutment • Temporary Cylinder • Flat Temporary Cylinder <ul style="list-style-type: none"> • Plastic Abutment 	IIa





Cert. No.: 71220-2010-CE-KOR-NA
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Project No.: PRJC-35664-2007-PRC-KOR

	<ul style="list-style-type: none"> • Plastic Cylinder • Flat Plastic Cylinder • Kerator abutment • Fuse Abutment • Fixture Mount • Cover Screw • Flat Cover Screw • i-Gen Cover Screw • Healing Abutment • Esthetic Healing Abutment • Flat Healing Abutment • Extra Healing Abutment • Scan Healing Abutment • Abutment Screw • Regular Abutment Screw • Wide Abutment Screw • Multi-unit Abutment Screw • Scan Healing Abutment Screw • Gold Screw • Cylinder Screw • Flat Cylinder Screw • Multi Post Screw • Closing Screw • Mount Screw • Multi Mount Screw • Multi Mount Sealing Screw • i-Gen Screw • Healing Cap • Octa Healing Cap • Solid Cap • Comfort Cap • Multi Post Cap • Solid Post Cap • Fuse Cap • Retentive Caps • Stainless Steel Housing • Cap Assortment Kit 	
Accessory for dental implant surgery (stabilize and support of bone graft)	<ul style="list-style-type: none"> • i-Gen® 	IIa



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Surgical instrument	<ul style="list-style-type: none"> • Lance Drill • Lindermann Drill • Tissue Punch • Twist Drill • Straight Drill • Stopper Drill • Second Drill • Marking Drill • Intermezzo Drill • Pilot Drill • Shaping Drill • Tap • Countersink • Bottom Drill • Coronal Drill • Cortical Bone Drill • Cortical Drill Tip • Point Trephine Bur • ASBE Trephine • Trephine Bur • Trephine Bur Stopper • Bone Profiler • Diamond Drill • Reamer Drill • Bone Expander • Surgical Instrument Kit Case • Dense Drill • Initial Guide Drill • Express Bur • Auto-Max • Initial Drill • Anchor Pin • EZ Draw • Flattening Lance • Flattening Drill Housing • Flattening Drill • Narrow Crest Drill 	Ila
Harvest device for Soft Tissue	<ul style="list-style-type: none"> • Soft Tissue Harvester 	Ila
Surgical instrument with measuring function	<ul style="list-style-type: none"> • Depth Gauge • Sinus Lift Instrument • Restome • Megatome 	Im





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• **Surgical Instrument Kit Case**

Sites covered by this certificate

Site Name	Address
MegaGen Implant Co., Ltd.	472, Hanjanggun-ro, Jain-myeon, Gyeongsan-si, Gyeongsangbuk-do, Korea, Republic of, 712-852

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