

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10888-2017-CE-KOR-NA-PS Rev. 6.0

Project No.:
PRJC-35664-2007-MSL-KOR

Valid Until:
08 March 2021

This is to certify that the quality system of:

MegaGen Implant Co., Ltd.

45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu 42921, Republic of 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 ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 03 June 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate 71220-2010-CE-KOR-NA Rev. 14.0 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	19 October 2017
1.0	Scope extension	27 June 2018
2.0	Site re-location, change of address	13 July 2018
3.0	Scope extension	10 August 2018
4.0	Scope extension	27 November 2019
5.0	Change in product name and model deletion	02 June 2020
6.0	Editorial change (typo error)	03 June 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Dental Implants	<ul style="list-style-type: none"> ▪ Advanced Intermezzo® Fixture ▪ XPEED® AnyRidge® Internal Fixture ▪ AnyOne® External Fixture ▪ AnyOne® Internal Fixture ▪ MiNi® Internal Fixture ▪ MiNi® Overdenture Fixture ▪ BlueDiamond Fixture ▪ AnyOne® Onestage Fixture ▪ ST Internal Fixture 	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 ▪ Multi Post ▪ Solid Abutment ▪ Octa Abutment ▪ Milling Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package 	IIb

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	<ul style="list-style-type: none"> ▪ 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-Loc Abutment ▪ Meg-Rhein Overdenture System 	
	<ul style="list-style-type: none"> ▪ Temporary Abutment ▪ Temporary Cylinder ▪ Flat Temporary Cylinder ▪ Plastic Abutment ▪ Plastic Cylinder ▪ Flat Plastic Cylinder ▪ Kerator abutment ▪ Fuse Abutment ▪ 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 ▪ Multi-unit Abutment Screw ▪ Scan Healing Abutment Screw ▪ Gold Screw ▪ Cylinder Screw ▪ Flat Cylinder Screw ▪ Multi Post Screw ▪ Closing Screw ▪ Mount Screw ▪ i-Gen Screw ▪ Healing Cap ▪ Octa Healing Cap ▪ Solid Cap ▪ Comfort Cap ▪ Multi Post Cap ▪ Solid Post Cap 	<p>IIa</p>

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	<ul style="list-style-type: none"> ▪ 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
Surgical instrument	<ul style="list-style-type: none"> ▪ Lance Drill ▪ Lindermann Drill ▪ Tissue Punch ▪ Stopper Drill ▪ Second Drill ▪ Marking Drill ▪ Intermezzo Drill ▪ Shaping Drill ▪ Tap ▪ Bottom Drill ▪ Cortical Bone Drill ▪ Cortical Drill Tip ▪ Point Trepine Bur ▪ ASBE Trepine ▪ Trepine Bur ▪ Stopper ▪ Bone Profiler ▪ Diamond Drill ▪ Bone Expander ▪ Surgical Instrument Kit Case ▪ Dense Drill ▪ Initial Guide Drill ▪ Express Bur ▪ Auto-Max ▪ Initial Drill ▪ Anchor Pin ▪ Flattening Lance ▪ Flattening Drill Housing ▪ Flattening Drill ▪ Narrow Crest Drill 	IIa
Surgical instrument with measuring function	<ul style="list-style-type: none"> ▪ Depth Gauge ▪ Sinus Lift Instrument ▪ Restome ▪ Megatome ▪ Surgical Instrument Kit Case 	Im

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Site Name	Address
Head Office & Factory 1(Daegu)	45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu 42921, Republic of Korea
Factory 2(Gyeong-san)	472, Hanjanggun-ro, Jain-myeon, Gyeongsan-si, Gyeongsangbuk-do 38552, Republic of Korea

EU Representative

MDSS GmbH, Schiffgraben 41 30175 Hannover, Germany

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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 Presafe.

End of Certificate