EU Quality Management System Certificate

Certificate no.:
C554490 NoMA KOR

Initial certification date:
29 November 2022

Valid Until:
29 November 2027

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
SRN: KR-MF-000009885

For design, production and final product inspection/testing of:

Sterile Dental Implant System

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I, II, III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 29 November 2022

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Mariann Jeremiassen
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com
MCR-CO-078-A V0.4

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2582618	29 November 2022

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name		Class*
XPEED AnyRidge Internal Implant System **Intended purpose:** The XPEED AnyRidge Internal Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients	-XPEED AnyRidge Internal Fixture -EZ Post Abutment -Extra EZ Post Abutment -Angled Abutment -Solid Abutment -Milling Abutment -Octa Abutment -Meg-Rhein Abutment -Meg-Rhein Overdenture System -Multi-unit Abutment -Flat Abutment -Multi-unit Angled Abutment -Multi-unit Abutment Package -CCM Abutment -CCM Cylinder -EZ Post Cylinder -Flat EZ Post Cylinder -Flat CCM Cylinder -Cover Screw -Healing Abutment -Extra Healing Abutment -Scan Healing Abutment	-S.H.A Screw -Abutment Screw -Temporary Abutment -Comfort Cap -Fuse Abutment -Fuse Cap -Multi Post Screw -Multi-unit Abutment Screw -Flat Healing Abutment -Flat Temporary Cylinder -Flat Plastic Cylinder -Healing Cap -Temporary Cylinder -Plastic Cylinder -Cylinder Screw -Flat Cover Screw -Flat Cylinder Screw -TiGEN Abutment -ZrGEN Abutment -Meg-Ball Abutment -Meg-Ball Package -Meg-Loc Abutment -Multi-unit Abutment Set -Multi-unit Healing Cap Set	IIb implantable

	-Retentive Cap -Stainless Steel Housing -Retentive Ring -Metal Cap -Metal Housing -Meg-Rhein Overdenture System	IIa

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: C567556 NoMA KOR

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
MegaGen Implant Co.,Ltd	45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, 42921, 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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

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

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.

Conformity declaration and marking of product

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