EU Technical Documentation Assessment Certificate

Certificate no.:
C624314

Initial certification date:
15 November 2023

Valid Until:
14 November 2028

This is to certify that:
AnyOne Internal Implant System

Manufactured by:

MegaGen Implant Co.,Ltd

45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, 42921, Republic of Korea
SRN: KR-MF-000009885

Has been assessed and found to comply with respect to:

Technical Documentation Assessment as described in Annex IX (Chapter I&II&III) of Regulation 2017/745 on Medical Devices

Place and date:
Høvik, 15 November 2023

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

Tone Kolpus

Tone Elise Kolpus
Management Representative

Certificate no.: C624314
Place and date: Høvik, 15 November 2023

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	2779261	15 November 2023

Products covered by this Certificate:

Type of medical device and identification no., Basic UDI-DI		Class	EMDN code
Basic UDI-DI	880972899062P	IIb implantable	P010201

[AnyOne Internal Implant System consisted with below components]

- AnyOne Internal Fixture
- EZ Post Abutment
- Angled Abutment
- Solid Abutment
- Milling Abutment
- Octa Abutment
- Meg-Rhein Abutment
- Meg-Rhein Overdenture System
- Multi-unit Abutment
- Multi-unit Abutment Package
- Multi-unit Angled Abutment
- Flat Abutment
- CCM Abutment
- CCM Cylinder
- EZ Post Cylinder
- Flat EZ Post Cylinder
- Flat CCM Cylinder
- TiGEN Abutment
- ZrGEN Abutment
- Cover Screw
- Healing Abutment
- Scan Healing Abutment
- S.H.A Screw
- Temporary Abutment
- Comfort Cap
- Fuse Abutment
- Fuse Cap
- Abutment 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
- Meg-Ball Abutment
- Meg-Ball Package
- Meg-Loc Abutment
- Multi-unit Abutment Set
- Multi-unit Healing Cap Set

Intended purpose of the Medical Device

The AnyOne Internal Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients.

Conformity Assessment for devices listed is covered by separate EU Quality Management System Certificate No.: C554490 NoMA KOR

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 inform the Notified Body of any intended change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EU Quality Management System Certificate.

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.