DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10888-2017-CE-KOR-NA-PS Rev. 7.0	PRJC-35664-2007-MSL-KOR	27 May 2024

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, 22 December 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Palani Damodharan

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

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
7.0	**Recertification**	**22 December 2020**

Products covered by this Certificate:

Product Description	**Product Name**	**Class**
XPEED AnyRidge Internal Implant System	▪ XPEED AnyRidge Internal Fixture ▪ Gold Abutment ▪ 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 ▪ Gold Cylinder ▪ Flat EZ Post Cylinder ▪ Flat Gold Cylinder ▪ Flat CCM Cylinder ▪ Cover Screw ▪ Healing Abutment ▪ Extra Healing Abutment	IIb

	▪ Scan Healing Abutment ▪ Scan Healing Abutment 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	
	▪ Retentive Caps ▪ Stainless Steel Housing ▪ Retentive Ring ▪ Metal Cap ▪ Metal Housing ▪ Meg-Rhein Overdenture System	IIa
AnyOne Internal Implant System	▪ AnyOne Internal Fixture ▪ Gold Abutment ▪ 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 ▪ Gold Cylinder ▪ Flat EZ Post Cylinder ▪ Flat Gold Cylinder ▪ Flat CCM Cylinder ▪ Cover Screw	IIb

	▪ Healing Abutment ▪ Scan Healing Abutment ▪ Scan Healing Abutment 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 ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment	
	▪ Retentive Caps ▪ Stainless Steel Housing ▪ Meg-Rhein Overdenture System ▪ Retentive Ring ▪ Metal Cap ▪ Metal Housing	IIa
AnyOne External Implant System	▪ AnyOne External Fixture ▪ EZ Post Abutment ▪ EZ Post Cylinder ▪ Angled Abutment ▪ Gold Abutment ▪ Gold Cylinder ▪ CCM Cylinder ▪ Plastic Cylinder ▪ Regular Abutment ▪ Meg-Rhein Abutment ▪ Meg-Rhein Overdenture System ▪ Milling Abutment ▪ Multi-unit Abutment ▪ Multi-unit Abutment Screw ▪ Multi-unit Angled Abutment ▪ Multi-unit Abutment Package ▪ Mount Screw ▪ Cover Screw ▪ Healing Abutment ▪ Esthetic Healing Abutment ▪ Abutment Screw ▪ Temporary Abutment ▪ Temporary Cylinder ▪ Plastic Abutment ▪ Gold Screw	IIb

	▪ Regular Abutment Screw ▪ Healing Cap ▪ Cylinder Screw ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Fixture Mount	
	▪ Retentive Caps ▪ Stainless Steel Housing ▪ Meg-Rhein Overdenture System	IIa
BLUEDIAMOND Implant System	▪ BLUEDIAMOND IMPLANT ▪ EZ Post Abutment ▪ Angled Abutment ▪ Milling Abutment ▪ Octa Abutment ▪ Meg-Rhein Abutment ▪ Meg-Rhein Overdenture System ▪ Multi-unit Abutment ▪ Multi-unit Angled Abutment ▪ Multi-unit Abutment Package ▪ CCM Abutment ▪ Cover Screw ▪ Healing Abutment ▪ Scan Healing Abutment ▪ Scan Healing Abutment Screw ▪ CCM Cylinder ▪ Gold Cylinder ▪ Plastic Cylinder ▪ EZ Post Cylinder ▪ Cylinder Screw ▪ Temporary Cylinder ▪ Temporary Abutment ▪ Fixture Mount ▪ Fuse Abutment ▪ Fuse Cap ▪ Multi-unit Abutment Screw ▪ Abutment Screw ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment ▪ Comfort Cap ▪ Healing Cap	IIb
	▪ Retentive Caps ▪ Stainless Steel Housing ▪ Retentive Ring ▪ Metal Cap ▪ Metal Housing ▪ Meg-Rhein Overdenture System	IIa
MiNi Internal Implant System	▪ MiNi Internal Fixture ▪ EZ Post Abutment ▪ Milling Abutment	IIb

	▪ Solid Abutment ▪ Angled Abutment ▪ Meg-Rhein Abutment ▪ Meg-Rhein Overdenture System ▪ Cover Screw ▪ Healing Abutment ▪ Temporary Abutment ▪ Fuse Abutment ▪ Fuse Cap ▪ Abutment Screw ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment	
	▪ Retentive Caps ▪ Stainless Steel Housing ▪ Retentive Ring ▪ Metal Cap ▪ Metal Housing ▪ Meg-Rhein Overdenture System	IIa
ST Internal Implant System	▪ ST Internal Fixture ▪ EZ Post Abutment ▪ Angled Abutment ▪ Solid Abutment ▪ Milling Abutment ▪ Cover Screw ▪ Healing Abutment ▪ Temporary Abutment ▪ Abutment Screw ▪ Comfort Cap ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment	IIb
	▪ Retentive ring ▪ Metal Cap ▪ Metal Housing	IIa
AnyOne Onestage Implant System	▪ AnyOne Onestage Fixture ▪ EZ Post Abutment ▪ Multi Post ▪ Multi Post Cap ▪ Multi Post Screw ▪ Closing Screw ▪ Cover Screw ▪ Healing Abutment ▪ Healing Cap ▪ Abutment Screw ▪ Multi-unit Abutment Screw ▪ Multi-unit Abutment Package ▪ Angled Abutment ▪ Gold Abutment	IIb

	▪ Solid Abutment ▪ Solid Cap ▪ Solid Post Abutment ▪ Solid Post Cap ▪ Octa Abutment ▪ Meg-Rhein Abutment ▪ CCM Abutment ▪ Meg-Rhein Overdenture System ▪ CCM Cylinder ▪ Gold Cylinder ▪ Plastic Cylinder ▪ EZ Post Cylinder ▪ Cylinder Screw ▪ Temporary Cylinder ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment ▪ Multi-unit Abutment ▪ Multi-unit Angled Abutment	
	▪ Retentive Caps ▪ Stainless Steel Housing ▪ Retentive Ring ▪ Metal Cap ▪ Metal Housing ▪ Meg-Rhein Overdenture System	IIa
MiNi Overdenture Implant System	▪ MiNi Overdenture Fixture	IIb
	▪ Retentive Caps ▪ Stainless Steel Housing ▪ Meg-Rhein Overdenture system	IIa
Advanced Intermezzo Implant System	▪ Advanced Intermezzo Fixture ▪ Comfort Cap	IIb
i-Gen System	▪ i-Gen ▪ i-Gen Cover screw ▪ i-Gen screw	IIb
Surgical instrument	▪ Lance Drill ▪ Lindermann Drill ▪ Tissue Punch ▪ Stopper Drill ▪ Second Drill ▪ Marking Drill ▪ Intermezzo Drill ▪ Shaping Drill ▪ Tap Drill ▪ Bottom Drill ▪ Cortical Bone Drill ▪ Cortical Drill Tip ▪ Point Trephine Bur ▪ ASBE Trephine ▪ Trephine Bur ▪ Stopper	IIa

	▪ Bone Profiler ▪ Bone Profiler Guide Pin ▪ Diamond Drill ▪ Bone Expander ▪ Surgical Instrument Kit ▪ Dense Drill ▪ Initial Guide Drill ▪ Express Bur ▪ Auto-Max ▪ Initial Drill ▪ Anchor Pin ▪ Flattening Lance ▪ Flattening Drill Housing ▪ Flattening Drill ▪ Narrow Crest Drill ▪ M-Bur	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
Head Office & Factory (Daegu)	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 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

APPENDIX TO EC CERTIFICATE

Certificate no.:
10888-2017-CE-KOR-NA-PS Rev. 7.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
MegaGen Implant Co., Ltd.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

There are no changes to the devices or the certification. This appendix has been issued to correct the blockchain QR code.

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Editorial change due to NGPS QR code error (certificate validity has not been updated correctly)	23 May 2023

Place and date:
Høvik, 23 May 2023

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

Hazem Tinawi
Technical Reviewer

Notified Body Confirmation Letter Reference: C699438

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MegaGen Implant Co., Ltd.
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun,
Daegu 42921, Republic of Korea

SRN Number KR-MF-000009885

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 27.07.2024

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

Menaka Singh
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Dental Implant System (BLUEDIAMOND IMPLANT System) **Device name** [Class IIb] - BLUEDIAMOND IMPLANT - EZ Post Abutment - Angled Abutment - Milling Abutment - Octa Abutment - Multi-unit Abutment - Multi-unit Angled Abutment - Multi-unit Abutment Set - Multi-unit Healing Cap Set - Meg-Rhein Abutment - Meg-Rhein Overdenture System - CCM Abutment - Meg-Ball Abutment - Meg-Ball Package - Meg-Loc Abutment - TiGEN Abutment - ZrGEN Abutment - Cover Screw - Healing Abutment - Scan Healing Abutment - S.H.A Screw	Class IIb implantable system (IIb, IIa components)	[Class IIb] ▪ BLUEDIAMOND IMPLANT ▪ EZ Post Abutment ▪ Angled Abutment ▪ Milling Abutment ▪ Octa Abutment ▪ Meg-Rhein Abutment ▪ Meg-Rhein Overdenture System ▪ Multi-unit Abutment ▪ Multi-unit Angled Abutment ▪ Multi-unit Abutment Package ▪ CCM Abutment ▪ Cover Screw ▪ Healing Abutment ▪ Scan Healing Abutment ▪ Scan Healing Abutment Screw ▪ CCM Cylinder ▪ Plastic Cylinder ▪ EZ Post Cylinder ▪ Cylinder Screw ▪ Temporary Cylinder ▪ Temporary Abutment ▪ Fuse Abutment ▪ Fuse Cap ▪ Multi-unit Abutment Screw	Certificate number : 10888-2017-CE-KOR-NA-PS Rev. 7.0 NB Identification : DNV Product Assurance AS (2460)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- Temporary Abutment - Fuse Abutment - Multi-unit Abutment Screw - Abutment Screw - Cylinder Screw - Comfort Cap - Fuse Cap - Healing Cap - CCM Cylinder - Plastic Cylinder - Temporary Cylinder - EZ Post Cylinder [Class IIa] - Retentive Cap - Retentive Ring - Stainless Steel Housing - Metal Cap - Metal Housing - Meg-Rhein Overdenture System **Basic UDI-DI** : 880972899082T		▪ Abutment Screw ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment ▪ Comfort Cap ▪ Healing Cap [Class IIa] ▪ Retentive Caps ▪ Stainless Steel Housing ▪ Retentive Ring ▪ Metal Cap ▪ Metal Housing ▪ Meg-Rhein Overdenture System (only name change)	
Dental Implant System (MiNi Internal Implant System) **Device name** [Class IIb] - MiNi Internal Fixture - EZ Post Abutment - Milling Abutment - Angled Abutment - Meg-Rhein Abutment - Meg-Rhein Overdenture System - Meg-Loc Abutment - Meg-Ball Abutment - Meg-Ball Package - TiGEN Abutment - ZrGEN Abutment - Cover Screw - Healing Abutment - Temporary Abutment - Fuse Abutment - Fuse Cap - Abutment Screw	Class IIb implantable system (IIb, IIa components)	[Class IIb] ▪ MiNi Internal Fixture ▪ EZ Post Abutment ▪ Milling Abutment ▪ Angled Abutment ▪ Meg-Rhein Abutment ▪ Meg-Rhein Overdenture System ▪ Cover Screw ▪ Healing Abutment ▪ Temporary Abutment ▪ Fuse Abutment ▪ Fuse Cap ▪ Abutment Screw ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment [Class IIa] ▪ Retentive Caps ▪ Stainless Steel Housing ▪ Retentive Ring	Certificate number : 10888-2017-CE-KOR-NA-PS Rev. 7.0 NB Identification : DNV Product Assurance AS (2460)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[Class IIa] - Retentive Cap - Retentive Ring - Stainless Steel Housing - Metal Cap - Metal Housing - Meg-Rhein Overdenture System **Basic UDI-DI** : 880972899092V		▪ Metal Cap ▪ Metal Housing ▪ Meg-Rhein Overdenture System (only name change)	
Dental Implant System (ST Internal Implant System) **Device name** [Class IIb] - ST Internal Fixture - EZ Post Abutment - Solid Abutment - Angled Abutment - Milling Abutment - Meg-Loc Abutment - Meg-Ball Abutment - Meg-Ball Package - TiGEN Abutment - ZrGEN Abutment - Cover Screw - Healing Abutment - Temporary Abutment - Abutment Screw [Class IIa] - Retentive Ring - Metal Cap - Metal Housing **Basic UDI-DI** : 880972899102E	Class IIb implantable system (IIb, IIa components)	[Class IIb] ▪ ST Internal Fixture ▪ EZ Post Abutment ▪ Angled Abutment ▪ Solid Abutment ▪ Milling Abutment ▪ Cover Screw ▪ Healing Abutment ▪ Temporary Abutment ▪ Abutment Screw ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment [Class IIa] ▪ Retentive ring ▪ Metal Cap ▪ Metal Housing (only name change)	Certificate number : 10888-2017-CE-KOR-NA-PS Rev. 7.0 NB Identification : DNV Product Assurance AS (2460)
Dental Implant System (AnyOne Onestage Implant System) **Device name** [Class IIb] - AnyOne Onestage Fixture - Multi Post	Class IIb implantable system (IIb, IIa components)	[Class IIb] ▪ AnyOne Onestage Fixture ▪ EZ Post Abutment ▪ Multi Post ▪ Multi Post Cap ▪ Multi Post Screw ▪ Closing Screw ▪ Cover Screw	Certificate number : 10888-2017-CE-KOR-NA-PS Rev. 7.0 NB Identification : DNV Product Assurance AS (2460)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- Angled Abutment - Solid Abutment - Solid Post Abutment - Octa Abutment - Meg-Rhein Abutment - Meg-Rhein Overdenture System - CCM Cylinder - Meg-Ball Abutment - Meg-Ball Package - Meg-Loc Abutment - TiGEN Abutment - ZrGEN Abutment - EZ Post Abutment - CCM Abutment - EZ Post Cylinder - Closing screw - Cover screw - Healing Abutment - Multi Post Screw - Abutment Screw - Healing Cap - Multi-unit Abutment Screw - Multi-unit Healing Cap Set - Multi Post Cap - Solid Cap - Solid Post Cap - Temporary Cylinder - Plastic Cylinder - Cylinder Screw [Class IIa] - Retentive Cap - Retentive Ring - Stainless Steel Housing - Metal Cap - Metal Housing - Meg-Rhein Overdenture System **Basic UDI-DI** : 880972899112G		▪ Healing Abutment ▪ Healing Cap ▪ Abutment Screw ▪ Multi-unit Abutment Screw ▪ Angled Abutment ▪ Solid Abutment ▪ Solid Cap ▪ Solid Post Abutment ▪ Solid Post Cap ▪ Octa Abutment ▪ Meg-Rhein Abutment ▪ CCM Abutment ▪ Meg-Rhein Overdenture System ▪ CCM Cylinder ▪ Plastic Cylinder ▪ EZ Post Cylinder ▪ Cylinder Screw ▪ Temporary Cylinder ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Meg-Ball Abutment ▪ Meg-Ball Package ▪ Meg-Loc Abutment ▪ Multi-unit Abutment Package [Class IIa] ▪ Retentive Caps ▪ Stainless Steel Housing ▪ Retentive Ring ▪ Metal Cap ▪ Metal Housing ▪ Meg-Rhein Overdenture System (only name change)	
Dental Implant System (AnyOne External Implant System) **Device name**	Class IIb implantable system (IIb, IIa components)	[Class IIb] ▪ AnyOne External Fixture ▪ EZ Post Abutment ▪ EZ Post Cylinder ▪ Angled Abutment ▪ CCM Cylinder	Certificate number : 10888-2017-CE-KOR-NA-PS Rev. 7.0 NB Identification :

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[Class IIb] - AnyOne External Fixture - EZ Post Abutment - EZ Post Cylinder - Angled Abutment - CCM Cylinder - Regular Abutment - Meg-Rhein Abutment - Meg-Rhein Overdenture System - Milling Abutment - Multi-unit Abutment - Multi-unit Angled Abutment - Multi-unit Abutment Set - Multi-unit Abutment Package - Multi-unit Healing Cap Set - TiGEN Abutment - ZrGEN Abutment - Fixture Mount - Mount Screw - Cover Screw - Healing Abutment - Esthetic Healing Abutment - Abutment Screw - Temporary Abutment - Temporary Cylinder - Plastic Abutment - Regular Abutment Screw - Healing Cap - Cylinder Screw - Multi-unit Abutment Screw - Plastic Cylinder [Class IIa] - Retentive Cap - Stainless Steel Housing - Meg-Rhein Overdenture System **Basic UDI-DI** : 880972899072R		▪ Plastic Cylinder ▪ Regular Abutment ▪ Meg-Rhein Abutment ▪ Meg-Rhein Overdenture System ▪ Milling Abutment ▪ Multi-unit Abutment ▪ Multi-unit Abutment Screw ▪ Multi-unit Angled Abutment ▪ Multi-unit Abutment Package ▪ Mount Screw ▪ Cover Screw ▪ Healing Abutment ▪ Esthetic Healing Abutment ▪ Abutment Screw ▪ Temporary Abutment ▪ Temporary Cylinder ▪ Plastic Abutment ▪ Regular Abutment Screw ▪ Healing Cap ▪ Cylinder Screw ▪ TiGEN Abutment ▪ ZrGEN Abutment ▪ Fixture Mount [Class IIa] ▪ Retentive Caps ▪ Stainless Steel Housing ▪ Meg-Rhein Overdenture System (only name change)	DNV Product Assurance AS (2460)
Dental Implant System (i-Gen System)	Class IIb implantable	N/A	Certificate number : 10888-2017-CE-KOR-

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name - i-Gen - i-Gen Screw - i-Gen Cover Screw **Basic UDI-DI** : 880972899142N			NA-PS Rev. 7.0 NB Identification : DNV Product Assurance AS (2460)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: (Delete if Not Applicable)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.07.27	C699438	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.