SZUTEST

EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-1917101

Manufacturer:	**Megagen Implant Co., Ltd.** 45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, Republic of KOREA
Product(s):	**Dental Unit**
Model(s):	1. NEXT PRO 2. N2 (Mount A Type), N2 (Mount B Type), N2 (Cart A Type), N2 (Cart B Type)
Reference Report No:	MM0716-P001-R01, MM0716-P001-R02, MM0716-P002-R01, MM0716-P002-R03, MM0716-P004-R01, MM0716-P004-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

This EC certificate is valid till 2024-05-26.

Issue Date:	2019-06-20
Revision No.:	02 Rev.
Revision Date:	2021-05-21

Rukiye BALKAN
Deputy General Manager

This version of certificate has come into force on 23.03.2017 1/1 2195-MED-1917101 Rev. 02

FR.MED.28 R.05

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No.1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

CERTIFICATE INFO AMENDMENT

SERTİFİKA BİLGİ DEĞİŞİKLİĞİ

According to Article 120(3) of the Regulation (EU) 2017/745 on Medical Devices

(AB) 2017/745 Tıbbi Cihazlar Yönetmeliği Madde 120(3)'ye göre

Effected Certificate Number(s): *Etkilenen Sertifika Numarası(ları):*	**2195-MED-1917101**
Manufacturer: *Üretici*	**Megagen Implant Co., Ltd.** Head Office/Merkez: 45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, Republic of KOREA Factory/Fabrika: 17-18, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, Republic of KOREA
Product(s): *Ürün(ler)*	**Dental Unit**
Model(s): *Model(ler)*	**N2 (Mount A Type), N2 (Mount B Type), N2 (Cart A Type), N2 (Cart B Type)**
Reference Report No: *Referans Rapor No*	MM0716-P010-R01, MM0716-P010-R03
Definition of the Change: *Değişikliğin Tanımı*	**Address addition and scope reduction. The factory address has been added to the EC certificate and NEXT PRO model has been removed from the scope.**

SZUTEST, Notified Body 2195, declares and the above mentioned manufacturer has initiated an insignificant change according to Article 120(3) of (EU) 2017/745 and MDCG 2020-3 guidance and therefore the information on the effected 93/42/EEC certificate(s) has been changed as described above.

This document is a confirmation for authorities and cannot be used as other purposes.

2195 kimlik numaralı Onaylanmış Kuruluş SZUTEST, yukarıda belirtilen üreticinin (AB) 2017/745 Regülasyonu Madde 120(3)'e ve MDCG 2020-3 rehber dokümanına göre önemli olmayan bir değişiklik yürüttüğünü ve bu sebeple etkilenen 93/42/AT sertifika(lar)ındaki bilgilerin yukarıdaki gibi değiştiğini beyan eder.

Bu doküman yetkili otoriteler için bir onay niteliğinde olup farklı bir amaçla kullanılamaz.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date/*Yayın Tarihi:* 2023-05-18

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

CERTIFICATE INFO AMENDMENT

SERTİFİKA BİLGİ DEĞİŞİKLİĞİ

According to Article 120(3) of the Regulation (EU) 2017/745 on Medical Devices

(AB) 2017/745 Tıbbi Cihazlar Yönetmeliği Madde 120(3)'ye göre

Effected Certificate Number(s): **2195-MED-1917101**
Etkilenen Sertifika Numarası(ları):

Manufacturer: **Megagen Implant Co., Ltd.**
Üretici

Head Office/Merkez:	45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, Republic of KOREA
Factory/Fabrika:	17-18, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, Republic of KOREA
Research Lab. / Araştırma Lab. :	19, Alphacity1-ro 31-gil, Suseong-gu, Daegu, Republic of KOREA

Product(s): **Dental Unit**
Ürün(ler)

Model(s): **N2 (Mount B Type), N2 (Cart B Type)**
Model(ler)

Reference Report No: MM0716-P013-R01, MM0716-P013-R02
Referans Rapor No

Definition of the Change: **Address addition and scope reduction. The research lab. address has been added to the EC certificate and N2 (Mount A Type), N2 (Cart A Type), models have been removed from the scope.**
Değişikliğin Tanımı

SZUTEST, Notified Body 2195, declares and the above mentioned manufacturer has initiated an insignificant change according to Article 120(3) of (EU) 2017/745 and MDCG 2020-3 guidance and therefore the information on the effected 93/42/EEC certificate(s) has been changed as described above.

This document is a confirmation for authorities and cannot be used as other purposes.

2195 kimlik numaralı Onaylanmış Kuruluş SZUTEST, yukarıda belirtilen üreticinin (AB) 2017/745 Regülasyonu Madde 120(3)'e ve MDCG 2020-3 rehber dokümanına göre önemli olmayan bir değişiklik yürüttüğünü ve bu sebeple etkilenen 93/42/AT sertifika(lar)ındaki bilgilerin yukarıdaki gibi değiştiğini beyan eder.

Bu doküman yetkili otoriteler için bir onay niteliğinde olup farklı bir amaçla kullanılamaz.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date/*Yayın Tarihi:* 2024-07-09

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

10th May 2024

Subject: Official Notification on Extension of CE MDD Certificate according to Article 120 3c

Dear Sir or Madam

We, MegaGen Implant Co., Ltd. Inform that our CE MDD Certification has been extended to 31 December 2027 for Class IIb implantable device or 31 December 2028 for Class IIa device in accordance with the Article 120 (3) of Regulation (EU) 2017/745 and Regulation (EU) 2023/607.

The process by which we meet the Article 120 3c (a)~(e) is as follows.

PARAGRAPHS OF 3c	MegaGen's STATE	Judgment
(a) those devices continues to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;	MegaGen's PRODUCTs continues to comply with Directive 93/42/EEC.	☒
(b) there are no significant changes in the design and intended purpose;	There are no significant changes in the design and intended purpose to MegaGen's PRODUCTs which is certified MDD.	☒
(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;	MegaGen's PRODUCTs which is certified MDD do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.	☒
(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);	MegaGen Implant Co., Ltd. has put in place a QMS in accordance with Article 10(9).	☒
(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.	MegaGen Implant Co., Ltd. has lodged a MDR formal application for the MegaGen's PRODUCTs which is certified MDD with a NB. In addition, MegaGen Implant Co., Ltd. are going to sign the MDR agreement with NB by 26 September 2024.	☒

We, MegaGen Implant Co., Ltd. are also attaching Manufacturer's Self-Declaration that we are extending the MDD certification by meeting those paragraphs.

Yours Sincerely,

KWANG BUM PARK

Kwang-Bum Park, CEO of MegaGen Implant Co., Ltd
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu, Republic Of Korea