

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10856-2017-CE-KOR-NA-PS Rev. 3.0

Project No.:
PRJC-34732-2007-MSL-KOR

Valid Until:
27 May 2024

This is to certify that the quality system of:

OSSTEM IMPLANT Co., Ltd.

66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Korea 48002

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

Dental Implants & Surgical Devices

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, 09 October 2020

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

Cathrine Wisbech

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 24597-2009-CE-NOR Rev. 8.0 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	01 November 2017
1.0	EUR address change	23 November 2018
2.0	Brand name change	29 April 2019
3.0	Recertification	18 October 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Dental Implants	<ul style="list-style-type: none"> ▪ TS SA Implant System ▪ TS BA Implant System ▪ TS CA Implant System ▪ SS SA Implant System ▪ SS CA Implant System ▪ US SA Implant System ▪ US CA Implant System ▪ MS Implant System ▪ OrthAnchor System ▪ OssBuilder System 	IIb
Drill Systems	<ul style="list-style-type: none"> ▪ Surgical Dental Drill System 	IIa
Surgical Dental Kits	<ul style="list-style-type: none"> ▪ Surgical Dental Kit System 	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Haeundae Plant	66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Korea 48002
Warehouse	257, Digital-ro, Guro-gu, 08382, Seoul, Korea

EU Representative

DEUTSCHE OSSTEM GmbH., Mergenthalerallee 35-37, 65760, Eschborn, Germany

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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