



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 612000**

Issued To:

**A.B. Dental Devices Ltd.
19 Hayahalomim Street
Ashdod 77609
Israel**

In respect of:

The design development and manufacture of synthetic bone graft

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **24 March 2014**Date: **24 March 2014**Expiry Date: **23 March 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 612000**
Date: **24 March 2014**
Issued To: **A.B. Dental Devices Ltd.
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Date	Reference Number	Action
24 March 2014	8077577	First Issue

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Supplementary Information to CE 612000

Issued To:

**A.B. Dental Devices Ltd.
19 Hayahalomim Street
Ashdod 77609
Israel**

This certificate is issued under the OWN BRAND LABELLING process

OEM Information

Name	Kyungwon Medical Co., Ltd.
Address	Suite 601, World Meridian Venture Center, 60-24 Gasan-dong, Geumcheon-gu, Seoul, Korea 153-801
Notified Body	Det Norske Veritas No. 0434
Certificate No.	91129-2010-CE-KOR-NA
Scope	Design, production and final product inspection/testing of Synthetic Bone Graft, Bone Cement, Intervertebral Body Fusion Device, Pedicle Screw Implant System
Issue / Reissue Date	06 Jan 2011 / 18 Nov 2015
Route to Conformity	Annex II section 3.2

The Validity of this OBL certificate is conditional on the continuing validity of the Original Equipment Manufacturer's certification under the Medical Device Directive and the maintenance of the relevant controls exercised by the Own Brand Labeller

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.



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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 612000**
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Ashdod 77609
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Subcontractor:	Service(s) supplied
CEpartner4U BV Esdoornlaan 13 3951 DB Maarn Netherlands	EU Representative

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