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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 612000**

Date: **24 March 2014**

Issued To: **A.B. Dental Devices Ltd.**
19 Hayahalomim Street
Ashdod 77609
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Date	Reference Number	Action
24 March 2014	8077577	First Issue

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EC Certificate - Full Quality Assurance System

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

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

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 612000**

Date: **24 March 2014**

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

Subcontractor:	Service(s) supplied
CEpartner4U BV Esdoornlaan 13 3951 DB Maarn Netherlands	**EU Representative**

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