EC Design-Examination Certificate

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

No. **CE 578383**

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

In respect of:

Artificial Bone Substitute: BioFill-S

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **13 September 2011** Date: **24 March 2014** Expiry Date: **12 September 2016**

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Supplementary Information to CE 578383

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Catalogue No.
BioFill – 1g -s
BioFill – 1g -l
BioFill – 3g -s
BioFill – 3g -l

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Certificate History

Date	Reference Number	Action
13 September 2011	7728183	First Issue
24 March 2014	8077577	Change of address from "3 Habosem Street, Ashdod" to "19 Hayahalomim Street, Ashdod, 77609"

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This certificate is issued under the OWN BRAND LABELLING process
The corresponding Annex II, section 3.2 certificate is CE 612000
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	DNV
Certificate No.	91129-2010-CE-KOR-NA
Issue / Reissue Date	06 Jan 2011 / 18 Nov 2015
Route to Conformity	Annex II, Section 4 93/42/EEC

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: **13 September 2011** Date: **24 March 2014** Expiry Date: **12 September 2016**