



# 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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Page 1 of 3

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

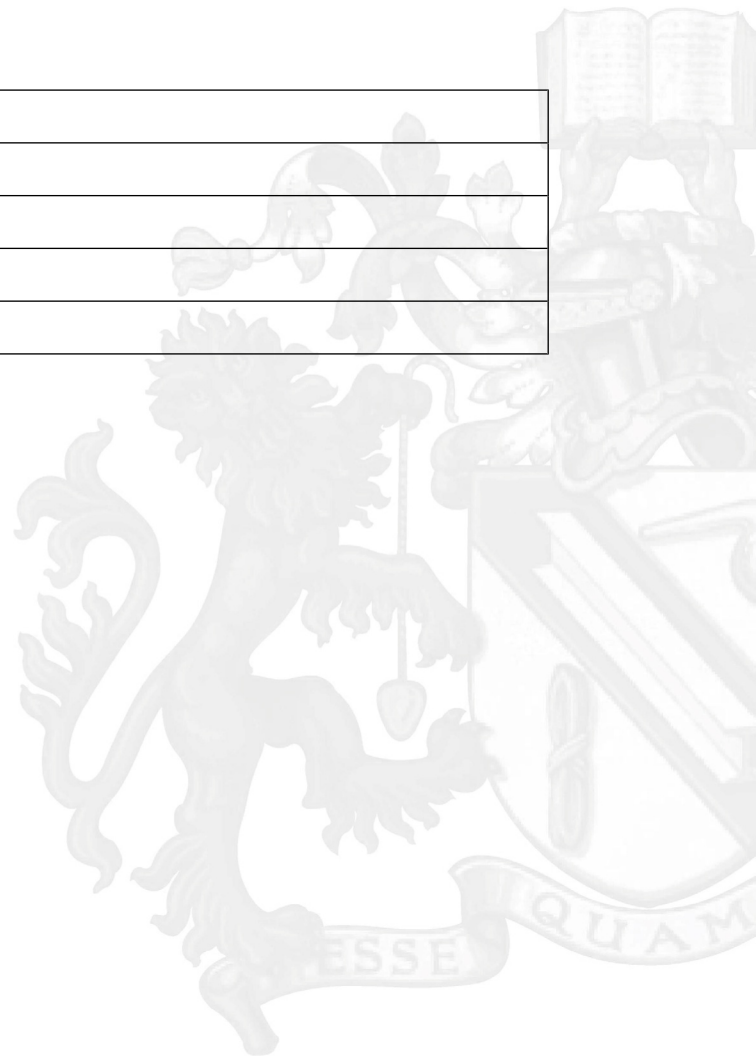
# EC Design-Examination Certificate

## Supplementary Information to CE 578383

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<b>Catalogue No.</b>
BioFill – 1g -s
BioFill – 1g -l
BioFill – 3g -s
BioFill – 3g -l



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Date:

**12 September 2016**

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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.

# EC Design-Examination Certificate

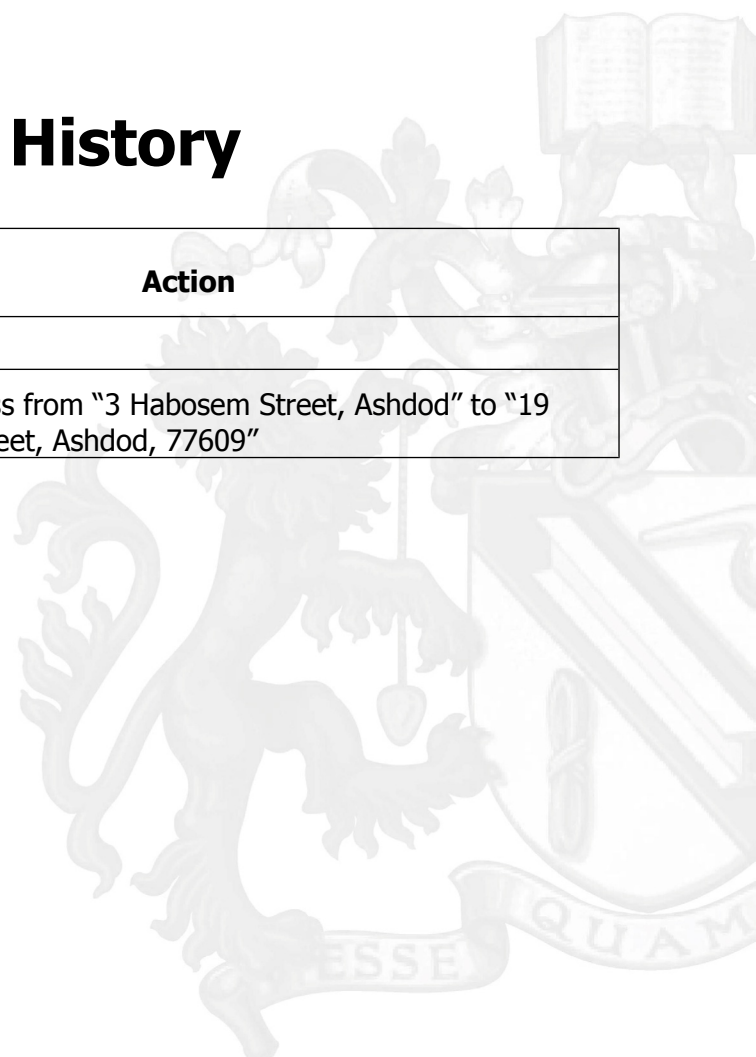
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## Certificate History

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"



First Issued: **13 September 2011**

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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**

<b>Name</b>	Kyungwon Medical Co., Ltd.
<b>Address</b>	Suite 601 World Meridian Venture Center, 60-24 Gasan-dong, Geumcheon-gu, Seoul, Korea 153-801
<b>Notified Body</b>	DNV
<b>Certificate No.</b>	91129-2010-CE-KOR-NA
<b>Issue / Reissue Date</b>	06 Jan 2011 / 18 Nov 2015
<b>Route to Conformity</b>	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

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