EC Design-Examination Certificate

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

No. **CE 577403**

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

In respect of:

BioSeal-S absorbable collagen membrane

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: **12 August 2011** Date: **24 March 2014** Expiry Date: **11 August 2016**

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Product Codes
Bioseal-S-1.5x2.0, 15mm x 20mm
Bioseal-S-3.0x4.0, 30mm x 40mm
Bioseal-S-1.5x3.0, 15mm x 30mm
Bioseal-S-2.5x2.5, 25mm x 25mm

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Certificate History

Date	Reference Number	Action
12 August 2011	7715738	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 611998

OEM Information

Name	BIOLAND Co., Ltd.
Address	644-6 Gak-ri Ochang Cheongwon Chungbuk 363-883 Korea
Notified Body	Institute for Testing and Certification, Inc.
Certificate No.	No. 09 0447 QS/NB/a
Issue / Reissue Date	28 July 2009 / 27 July 2014
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: **12 August 2011** Date: **24 March 2014** Expiry Date: **11 August 2016**