EC Certificate - Full Quality Assurance System

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

No. **CE 572724**

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

In respect of:

The Design, Development and Manufacture of Resin Cement for Implant Retained Crowns: AB-Cem

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: **01 July 2011** Date: **24 March 2014** Expiry Date: **24 May 2015**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 572724**

Date: **24 March 2014**

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

Date	Reference Number	Action
01 July 2011	7652990	First Issue
24 March 2014	8077577	Change of address from "3 Habosem Street, Ashdod" to "19 Hayahalomim Street, Ashdod, 77609"

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 572724

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	B.J.M. Laboratories Limited
Address	12 Hassadna Street Industrial Park Or-Yehuda 60200 Israel
Notified Body	Intertek
Certificate No.	134 CE
Issue / Reissue Date	26 Apr 1997 / 26 Apr 2012
Route to Conformity	Annex II, (excluding 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: **01 July 2011** Date: **24 March 2014** Expiry Date: **24 May 2015**

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 572724**

Date: **24 March 2014**

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

Subcontractor:	Service(s) supplied
CE PARTNER4U BV Esdoornlaan 13 3951DB Maarn Netherlands	**EU Representative**

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