

EC Certificate - Full Quality Assurance System

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

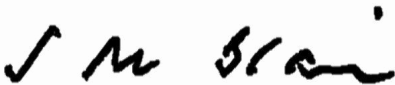
No. CE 572710
Issued To: **A.B. Dental Devices Ltd.**
19 Hayahalomim Street
Ashdod
7761117
Israel

In respect of:

Design, development and manufacture of dental implants, abutments and prosthetic accessories.

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):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2011-07-07**

Date: **2018-01-24**

Expiry Date: **2022-12-09**

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
CE PARTNER4U BV Esdoornlaan 13 3951DB Maarn The Netherlands	EU Representative
Sor-Van Irradiation Ltd. Kiryat Soreq PO Box 214 Yavne 81800 Israel	Gamma Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
7 July 2011	7652952	First issue
10 December 2012	7910174	Certificate Renewal
24 March 2014	8077577	Change of address from "3 Habosem Street, Ashdod" to "19 Hayahalomim Street, Ashdod, 77609"
Current	8857200	Certificate Renewal

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