EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 760512 R000

Manufacturer: A.B. Dental Devices Ltd.

Address:
19 Hayahalomim Street
Ashdod
7761117
Israel

Single Registration Number: IL-MF 000008766

EU Authorised Representative: CEpartner4U

Address:
Esdoornlaan 13
3951 DB Maarn
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-01-19**

Current Issue Date: **2023-08-24**

Starting Validity Date: **2023-08-24**

Expiry Date: **2028-01-18**

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Abutments	Intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained to the abutment.
Implant Accessories	Intended for use to connect sleeves, abutments and implants; support single or multiple tooth prostheses; and cover implant and abutments. The accessories can be cement retained to the abutment/sleeves.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Reusable Dental Instruments Connected to an Active Device	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-01-19	3564059	Issued
Current	3896734	Amended – Addition of Subcontractor for manufacture of Dental Drills. Supplemented – Addition of device category 'Reusable Dental Instruments Connected to an Active Device'.

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