



## Certificate of Registration

## OUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

A.B. Dental Devices Ltd. 19 Hayahalomim Street Ashdod 7761117 Israel

DUNS Number: 53-412-8491

Holds Certificate No:

**MDSAP 703564** 

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

> Design, Development and Manufacture of Dental Implants, Abutments and Prosthetic Accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-04-08

Effective Date: 2020-04-08

Expiry Date: 2023-04-07

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BSI Group America Inc. is an MDSAP authorized auditing organization

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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.





## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

A.B. Dental Devices Ltd. 19 Hayahalomim Street Ashdod 7761117 Israel

Holds Certificate No:

FM 704539

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture and inspection of Dental Implants and Prosthetic Accessories. The provision of 3D computerized treatment planning services.

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For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2011-07-08 Latest Revision Date: 2020-04-08





Effective Date: 2020-04-08 Expiry Date: 2023-04-07

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