

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

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



BSI Group America Inc. is an MDSAP authorized auditing organization

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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.

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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