

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973

File No. : HQ/MD/2020/000251

To,
M/s ABA Technologies, 2978, Ranjeet Nagar, Near
Shiv Chowk, South Patel Nagar (24), , Central Delhi,
Delhi (India) - 110008 Telephone No.: 011 45272788
FAX: 011 45272788

Dated : 02-JUL-2020

Sub:- Import Licence under the Medical Device Rules, 2017 thereunder- regarding.
Sir,

Import License No. IMP/MD/2020/000333 is hereby forwarded to you which is subjected to the following conditions:-

1. The provisions of Drugs and Cosmetics Act 1940 and Rules thereunder are in addition to and not derogation of any other law for the time being in force and as such the licence(s) issued under Drugs and Cosmetics Act and Rules will be in addition to and distinct from any licence(s) which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself / themselves be sufficient authority for import of Medical Devices covered by that / those licence(s) if under the Import Trade Control Regulations of the Commerce Ministry separate license(s) are required for import of such Medical Devices.
3. Therefore, it is advised to obtain, where necessary licence(s) for import of Medical Devices in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the Medical Devices or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The products and premises covered under this licence(s) are subjected to inspection by drugs regulatory officials as & when required.

Yours faithfully

VENUGOPAL
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Licensing Authority

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GIRDHARILA
DN: cn=, o=MINISTRY OF HOME AFFAIRS,
ou=GOVERNMENT OF INDIA, email=VENUGOPAL.GIRDHARILA@MHA.GOV.IN,
c=IN, serial=11585462486632764715
Date: 2020.07.02 10:36:45 +05'30'

FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. : IMP/MD/2020/000333

1. M/s ABA Technologies, 2978, Ranjeet Nagar, Near Shiv Chowk, South Patel Nagar (24), , Central Delhi, Delhi (India) - 110008 Telephone No.: 011 45272788 FAX: 011 45272788 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s A.B. Dental Devices Ltd. , 19 Hayahalomin Str. Ashod , Country: Israel Telephone No.: 97288522562 FAX: 97288531388 E-Mail : RA@AB-dent.com	Actual Manufacturing Site : M/s A.B. Dental Devices Ltd. , 19 Hayahalomin Str. Ashod , Country: Israel Telephone No.: 97288522562 FAX: 97288531388 E-Mail : RA@AB-dent.com

3. Details of medical device(s):

S.No	Medical Device Details
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serial=431461, st=Maharashtra,
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1

1. Generic Name :Titan Implant
2. Brand Name(if registered under the Trade Marks Act, 1999) :Titan Implant
3. Class of Medical Device :Class C
4. Shelf Life :6 Years
5. Sterile/Non-sterile: Sterilized
6. Intended Use :AB Dental Implants are dental implants intended to be used in the upper or lower jaw bone for anchoring and providing support to tooth replacements, such as artificial teeth, in order to restore chewing function.
7. Material of Construction: Titanium Alloy
8. Dimension: Various Dimension from Dimension (smallest) 5 to (Largest) 16
9. Model No. :Conical Implant - I5-3,8 I5-3,10 I5-3,11.5 I5-3,13 I5-3,16 I5-3.2,8 I5-3.2,10 I5-3.2,11.5 I5-3.2,13 I5-3.2,16 I5-3.3,10 I5-3.3,11.5 I5-3.3,13 I5-3.3,16 I5-3.5,8 I5-3.5,10, Conical Implant - I5-3.5,11.5 I5-3.5,13 I5-3.5,16 I5-3.75,8 I5-3.75,10 I5-3.75,11.5 I5-3.75,13 I5-3.75,16 I5-4.2,6 I5-4.2,8 I5-4.2,10 I5-4.2,11.5 I5-4.2,13 I5-4.2,16, Conical Implant - I5-4.5,6 I5-4.5,8 I5-4.5,10 I5-4.5,11.5 I5-4.5,13 I5-4.5,16 I5-5,6 I5-5,8 I5-5,10 I5-5,11.5 I5-5,13 I5-5,16 I5-6,6 I5-6,8 I5-6,10, Conical Implant - I5-6,11.5 I5-6,13 I5-6,16 I55-3,10 I55-3,11.5 I55-3,13 I55-3,16 I55-3.3,10 I55-3.3,11.5 I55-3.3,13 I55-3.3,16 I55-3.5,8 I55-3.5,10 I55-3.5,11.5 I55-3.5,13, Conical Implant - I55-3.5,16 I55-3.75,8 I55-3.75,10 I55-3.75,11.5 I55-3.75,13 I55-3.75,16 I55-4.2,8 I55-4.2,10 I55-4.2,11.5 I55-4.2,13 I55-4.2,16 I55-4.5,6 I55-4.5,8 I55-4.5,10 I55-4.5,11.5, Conical Implant - I55-4.5,13 I55-4.5,16 I55-5,6 I55-5,8 I55-5,10 I55-5,11.5 I55-5,13 I55-5,16, Conical Laser Implant - L5-3.3,10 L5-3.3,11.5 L5-3.3,13 L5-3.3,16 L5-3.75,8 L5-3.75,10 L5-3.75,11.5 L5-3.75,13 L5-3.75,16 L5-4.2,6 L5-4.2,8 L5-4.2,10 L5-4.2,11.5 L5-4.2,13 L5-4.2,16 L5-4.5,6, Conical Laser Implant - L5-4.5,8 L5-4.5,10 L5-4.5,11.5 L5-4.5,13 L5-4.5,16 L5-5,6 L5-5,8 L5-5,10 L5-5,11.5 L5-5,13 L5-5,16 L5-6,6 L5-6,8 L5-6,10 L5-6,11.5 L5-6,13 L5-6,16, Narrow Integral Implant - I6-2.4,11.5 I6-2.4,13 I6-2.4,16 I6-3,10 I6-3,11.5 I6-3,13 I6-3,16 I6-3.2,10 I6-3.2,11.5 I6-3.2,13 I6-3.2,16, One Piece Ball Attachment Implant - I6b-2.4,10 I6b-2.4,11.5 I6b-2.4,13 I6b-2.4,16, Integral Implant - I7-3.75,6 I7-3.75,8 I7-3.75,10 I7-3.75,11.5 I7-3.75,13 I7-3.75,16 I7-4.2,6 I7-4.2,8 I7-4.2,10 I7-4.2,11.5 I7-4.2,13 I7-4.2,16 I7-5,6 I7-5,8 I7-5,10 I7-5,11.5 I7-5,13 I7-5,16, Trapeze Implant - I10-3.75,8 I10-3.75,10 I10-3.75,11.5 I10-3.75,13 I10-3.75,16 I10-4.2,8 I10-4.2,10 I10-4.2,11.5 I10-4.2,13 I10-4.2,16 I10-4.5,8 I10-4.5,10 I10-4.5,11.5 I10-4.5,13 I10-4.5,16 I10-5,8 I10-5,10 I10-5,11.5 I10-5,13 I10-5,16, Trapeze Implant with conical platform - I10C-4.2,8 I10C-4.2,10 I10C-4.2,11.5 I10C-4.2,13 I10C-4.5,8 I10C-4.5,10 I10C-4.5,11.5 I10C-4.5,13 I10C-4.5,16 I10C-5,8 I10C-5,10 I10C-5,11.5 I10C-5,13 I10C-5,16, Short & wide Implant - I15-6,5, Screw Type Implant - I2-3.5,8 I2-3.5,10 I2-3.5,11.5 I2-3.5,13 I2-3.5,16 I2-3.75,8 I2-3.75,10 I2-3.75,11.5 I2-3.75,13 I2-3.75,16, Screw Type Implant - I2-4.2,8 I2-4.2,10 I2-4.2,11.5 I2-4.2,13 I2-4.2,16 I2-4.5,8 I2-4.5,10 I2-4.5,11.5 I2-4.5,13 I2-4.5,16, Screw Type Implant - I2-5,8 I2-5,10 I2-5,11.5 I2-5,13 I2-5,16 I2-6,8 I2-6,10 I2-6,11.5 I2-6,13 I2-6,16, Screw Type Implant - I22-3.75,8 I22-3.75,10 I22-3.75,11.5 I22-3.75,13 I22-3.75,16 I22-4.2,8 I22-4.2,10 I22-4.2,11.5 I22-4.2,13 I22-4.2,16 I22-5,8 I22-5,10 I22-5,11.5 I22-5,13 I22-5,16

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1. Generic Name :Dental Abutment with Screws and Healing caps
2. Brand Name(if registered under the Trade Marks Act, 1999) :Dental Abutment with Screws and Healing caps
3. Class of Medical Device :Class C
4. Shelf Life :NA
5. Sterile/Non-sterile:Non-Sterilized
6. Intended Use :Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patients chewing function
7. Material of Construction: Titanium Alloy
8. Dimension: Various Dimension from Dimension (smallest) 1 to (Largest) 45
9. Model No. :Ti Base Rotational Slim H3mm Narrow Platform - P3N-3,3,TIT,Ti Base Wide H0.8mm Narrow Platform - P3H-3,TIT,Flat Connection Abutment - P12-3.75,Narrow Anti-rotation Abutment - P3N-3.75,5 P3N-3.75,7 P3N-3.75,9,Narrow Anti-rotation Abutment with conical platform - P3NC-4,5 P3NC-4,7 P3NC-4,9,Anatomic Anti-rotation Abutment - P3S-3,1 P3S-3,2 P3S-3,3 P3S-3.75,1 P3S-3.75,2 P3S-3.75,3 PK-P3-3, 1 PK-P3-3, 2 PK-P3-3, 3 PK-P3-3.75, 1 PK-P3-3.75, 2 PK-P3-3.75, 3 PK-P3-3.75, 4,Anti-rotation Abutment with conical platform - P3SC-4,1 P3SC-4,2 P3SC-4,3 P3C-4,Temporary PEEK Anatomic Anti-rotation Abutment - P3S-PEEK-3,1 P3S-PEEK-3,2 P3S-PEEK-3,3 P3S-PEEK-3.75,1 P3S-PEEK-3.75,2 P3S-PEEK-3.75,3,Temporary PEEK Anatomic Anti-rotation Abutment with conical platform - P3SC-PEEK-4,1 P3SC-PEEK-4,2 P3SC-PEEK-4,3,Wide Anti-rotation Abutment - P3SW-3.75,1 P3SW-3.75,2 P3SW-3.75,3 P3W-3,9 P3W-3.75,9 P3W-3.75,12 P3W-3.75,15 P3W-3.75,9 P3W-3.75,12 P3W-3.75,15 P3W-3.75,9 P3W-3.75,12 P3W-3.75,15 P3W-3.75,12 P3W-3.75,15 P3W-3.75,15 P3W-3.75,9 P3W-3.75,12 P3W-3.75,15,Wide Anti-rotation Abutment with conical platform - P3SWC-4,1 P3SWC-4,2 P3SWC-4,3 P3WC-4,9 P3WC-4,12 P3WC-4,15,Angular Abutment 15 - P4-3,15 P4-3.75,15 P4-3.75,15st P4-5,15 P4-5,25,Angular Abutment 25 - P4-3,25 P4-3.75,25 P4-3.75,25st, Angular Abutment 25 Perfect Fit - P4-3.75,25-P,Angular Abutment 35 - P4-3.75,35,Angular Abutment 45 - P4-3.75,45,Angular Abutment 15 with conical platform - P4C-4,15,Angular Abutment 25 with conical platform - P4C-4,25,Long Angular Abutment 15 - P4L-3,15 P4L-3.75,15, Long Angular Abutment 25 - P4L-3,25 P4L-3.75,25,Long Angular Abutment 15 with conical platform - P4LC-4,15,Long Angular Abutment 25 with conical platform - P4LC-4,25,Narrow Angular Abutment 15 - P4N-3.75,15,Narrow Angular Abutment 15 with conical platform - P4NC-4,15,Anatomic Angular Abutment 15 with Shoulder - P4S-3,15-1 P4S-3,15-2 P4S-3,15-3 P4S-3.75,15-1 P4S-3.75,15-2 P4S-3.75,15-3,Anatomic Angular Abutment 25 with Shoulder - P4S-3.75,25-1 P4S-3.75,25-2 P4S-3.75,25-3,Anatomic Angular Abutment 15 with conical platform - P4SC-4,15,1 P4SC-4,15,2 P4SC-4,15,3,Anatomic Angular Abutment 25 with Shoulder with conical platform - P4SC-4,25,1 P4SC-4,25,2 P4SC-4,25,3,Temporary PEEK Anatomic Angular Abutment with conical platform - P4SC-PEEK-4,15,1 P4SC-PEEK-4,15,2 P4SC-PEEK-4,15,3 P4SC-PEEK-4,25,1 P4SC-PEEK-4,25,2 P4SC-PEEK-4,25,3,Wide Anatomic Angular Abutment 15 with Shoulder - P4SW-3.75,Wide Anatomic Angular Abutment 15 with Shoulder with conical platform - P4SWC-4,1 P4SWC-4,2 P4SWC-4,3,Zirconium Anatomic Angular Abutment - P4SZ-3,15,1 P4SZ-3,15,2 P4SZ-3,15,3 P4SZ-3.75,15,1 P4SZ-3.75,15,2 P4SZ-3.75,15,3 P4SZ-3.75,25,1 P4SZ-3.75,25,2 P4SZ-3.75,25,3,Ball Attachment Abutment - 5-3,1 5-3,2 5-3,3 5-3,4 5-3,5 5-3,6 P5-3.75,1 P5-3.75,2 P5-3.75,3 P5-3.75,4 P5-3.75,5 P5-3.75,6,Ball Attachment Abutment - a+b+c - P5-3set,1 P5-3set,2 P5-3set,3 P5-3set,4 P5-3set,5 P5-3set,6 P5-3.75set,1 P5-3.75set,2 P5-3.75set,3 P5-3.75 set,4 P5-3.75set,5 P5-3.75set,6,Angular Ball Attachment 20 - P5-3,20,1.5 P5-3,20,2 P5-3,20,3 P5-3,20,4 P5-3,20,5 P5-3,20,6 P5-3.75,20-1 P5-3.75,20-2 P5-3.75,20-3 P5-3.75,20-4 P5-3.75,20-5 P5-3.75,20-6,Angular Ball Attachment 20 - a+b+c - P5-3,20set,1.5 P5-3,20set,2 P5-

3,20set,3 P5-3,20set,4 P5-3,20set,5 P5-3,20set,6 P5-3.75,20set,1 P5-3.75,20set,2 P5-3.75,20set,3 P5-3.75,20set,4 P5-3.75,20set,5 P5-3.75,20set,6,Ball Attachment Abutment with conical platform - P5C-4,1 P5C-4,2 P5C-4,3 P5C-4,4 P5C-4,5 P5C-4,6,Ball Attachment Abutment with conical platform- a+ b+c - P5C-4set,1 P5C-4set,2 P5C-4set,3 P5C-4set,4 P5C-4set,5 P5C-4set,6, Aesthetic Abutment with Hex - P6H-3.75,0.5 P6H-3.75,1.5 P6H-3.75,3 P6H-3.75,4 P6H-3.75,5 P6H-3.75,6,Anti-rotation Aesthetic Abutment - P7-3.75,1 P7-3.75,2 P7-3.75,3,GOLD Composed NOT Hex Abutment - P9G-3.75,Composed Hex Abutment - P9H-3.75,GOLD Composed Hex Abutment - P9HG-3.75,COBALT CHROME Composed NOT Hex Abutment - P9R-3 P9R-3.75 , COBALT CHROME Composed Hex Abutment - P9HR-3 P9HR-3.75,Temporary Flat Connection Abutment - P12-3.75-T P12-3.75-T/L,Temporary Abutment for Immediate Loading - P15-3,1 P15-3,3 P15-3,5 P15-3.75,1 P15-3.75,2 P15-3.75,3 P15-3.75,4 P15-3.75,5 P15-3.75,6 P15-3.75,7,Plastic Snap Transfer with Abutment - D4-3, 1 D4-3, 2 D4-3, 3 D4-3.75,1 D4-3.75,2 D4-3.75,3 D4-3.75,4, Screw for abutment - P4a P4a-3 P4Ca P4a-S P3a-3,Screw for Abutment-Short - P3a,Screw for Abutment with Conical platform-Short - P3a-C,Screw for Abutment -Long - P3a-L,Screw for transfer D2-P14 - D2-P14a,Short fixing screw - D2a-3,Long fixing screw - D2al-3,Short fixing screw - D2a-3.75,Long fixing screw - D2al-3.75,Conical Fixing Screw - D2Ca-4,Long Conical Fixing Screw - D2Cal-4,Screw for P6H - P6Ha,Long Screw for P6H Screw - P6Hal P7a,1 P7a,2 P7a,3 P14a P14e, Screw for P12 - P12a,Screw for Angular adaptor - P64e,Fixation screw D-1.5 L-6.5 - FS-1.5,6.5 FS-1.5,8 FS-1.5,10,Fixation screw D-1.8 L-8 - FS-1.8,8 FS-1.8,10,Fixation screw D-2 L-7 - FS-2,7,Fixation screw D-2 L-9 - FS-2, 9,Fixation screw D-2 L-11 - FS-2.3, 11,Fixation screw D-2 L-13 - FS-2.3, 13, Fixation screw D-2.3 L-7 - FS-2.3,7,Fixation screw D-2.3 L-9 - FS-2.3, 9,Fixation screw D-2.3 L-11 - FS-2.3,11,Fixation screw D-2.3 L-13 - FS-2.3,13,Tapered screw for template - FS-13 FS-19,Plastic Sleeve Narrow w/Fixation Screw- Straight - P2N-3,15,Plastic sleeve w/Fixation Screw- Rounded - P2N-3.75,15 P2NH-3,15,Plastic sleeve w/Fixation Screw- Straight w/Hex - P2NH-3.75,15,Plastic sleeve w/Fixation Screw- Wide w/ex - P2WH-3.75,9,Titanium Healing Cap - P0-3,2 P0-3,3 P0-3,4 P0-3,5 P0-3,6 P0-3,7 P0-3.75,0.5 P0-3.75,2 P0-3.75,3 P0-3.75,4 P0-3.75,5 P0-3.75,6 P0-3.75,7, Titanium Healing Cap with conical platform - P0C-4,2 P0C-4,3 P0C-4,4 P0C-4,5,Narrow Titanium Healing Cap - P0N-3.75,2 P0N-3.75,3 P0N-3.75,4 P0N-3.75,5 P0N-3.75,6 P0N-3.75,7,Healing Cap for-P6H - P0-P6H,Healing Cap for-P14 - P0-P14,2.5 P0-P14,3.5 P0-P14,4 P0-P14,5 P0-P14,7, Healing Cap for-P24 - P0-P24,Healing Cap for-P64 - P0-P64,Wide Titanium Healing Cap - P0W-3.75,2 P0W-3.75,3 P0W-3.75,4 P0W-3.75,5 P0W-3.75,6,Anti-rotation Abutment - P3-3,9 P3-3,12 P3-3.75,5 P3-3.75,7 P3-3.75,9 P3-3.75,11 P3-3.75,12 P3-3.75,15 P3-5,5 P3-5,7 P3-5,9,Ti Base Slim Abutment H4mm Standard Platform - P3-3.75,TI,Ti Base Slim Abutment H4mm Standard Platform - P3-3.75,2,TI,Ti Base Slim Abutment H5mm Standard Platform - P3-3.75,3,TI,Ti Base Rotational Wide H0.8mm Standard Platform - P3-3.75,TIT,Ti Base Rotational Slim H0.6mm Standard Platform - P3N-3.75,0.6,TIT,Ti Base Rotational Slim H2mm Standard Platform - P3N-3.75,2,TIT,Ti Base Rotational Slim H3mm Standard Platform - P3N-3.75,3,TIT,Ti Base Wide H0.7mm Standard Platform - P3H-3.75,TIT,Ti Base Slim H0.8mm Narrow Platform - P3-3,TI,Ti Base Slim H2mm Narrow Platform - P3-3,2,TI,Ti Base Slim H3mm Narrow Platform - P3-3,3,TI,Ti Base Rotational Slim H3mm Narrow Platform - P3-3,TIT,Ti Base Rotational Slim H0.6mm Narrow Platform - P3N-3,0.6,TIT,Ti Base Rotational Slim H2mm Narrow Platform - P3N-3,2,TIT

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4. The authorised agent M/s ABA Technologies, 2978, Ranjeet Nagar, Near Shiv Chowk, South Patel Nagar (24), , Central Delhi, Delhi (India) - 110008 Telephone No.: 011 45272788 FAX: 011 45272788 will be responsible for the bussines activities of the overseas manufacturer, in India in all respects.
5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: New Delhi

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GIRDHARILA SOMANI
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GIRDHARILA SOMANI
Date: 2020.07.02 16:10:14 +05'30'

Central Licensing Authority





GOVERNMENT OF INDIA
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare
FDA BHAWAN, KOTLA ROAD, NEW DELHI (INDIA)

Form 41

(See Rule 27-A)

REGISTRATION CERTIFICATE

**REGISTRATION CERTIFICATE TO BE ISSUED FOR IMPORT OF DEVICES INTO INDIA UNDER
 DRUGS AND COSMETICS RULES 1945**

Registration Certificate No. MD-1220

1. **M/s. A.B. Dental Devices Ltd., 19, Hayahalomim Street, Ashdod, 7761117, Israel** having factory premises at **M/s. A.B. Dental Devices Ltd., 19, Hayahalomim Street, Ashdod, 7761117, Israel** has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration certificate.

2. Name(s) of device(s), which may be imported under this Registration Certificate.

S.No	Category	Device Details
1	Orthopaedic Implants	A. Generic Name: Dental Implant (Fixtures Screws) B. Brand Name: AB Dental C. Model No: NIL D. Contains Drug: No E. Components: NIL F. Intended Use: Implants are designed for prosthodontic reconstruction. They are to be inserted into areas of the maxillary or Mandibular arch locations for completely or partially edentulous patients. G. Shelf Life: 5.0 years
2	Orthopaedic Implants	A. Generic Name: Dental Implant (Abutments) B. Brand Name: AB Dental C. Model No: NIL D. Contains Drug: No E. Components: NIL F. Intended Use: Implants are designed for prosthodontic reconstruction. G. Shelf Life: 5.0 years

Place: New Delhi

LICENSING AUTHORITY

Date: **27-Jan-2017**

Page No.: 1

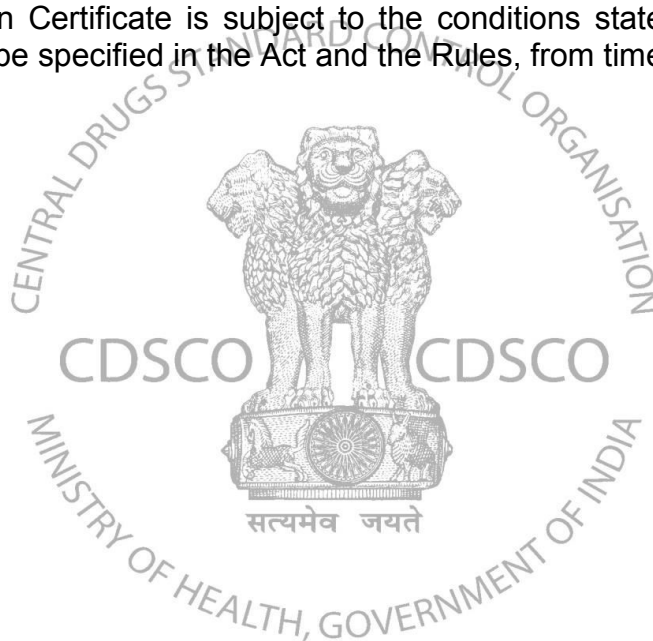
Seal/Stamp

S.No	Category	Device Details
3	Orthopaedic Implants	A. Generic Name: Dental Implant (Surgical Kits) B. Brand Name: AB Dental C. Model No: NIL D. Contains Drug: No E. Components: NIL F. Intended Use: Implants are designed for prosthodontic reconstruction. G. Shelf Life: 5.0 years

3. This Registration Certificate shall be in force from **16-Feb-2017** to **15-Feb-2020** unless it is sooner suspended or cancelled under the rules.

4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India **M/s Wellness Concepts, Shop No. 10, Om Apts, Sundervan Complex, Sub TV Lane, Link RD, Andheri West, Mumbai Zone 5- 400053, Maharashtra (India)** who will be responsible for the business activities of the manufacturer in India in all respects.

5. This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.



Place: New Delhi

LICENSING AUTHORITY

Date: 27-Jan-2017

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Conditions of the Registration

1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.
2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.
3. The manufacturer or his authorised agent in India shall comply with the conditions of the import License issued under the Drugs and Cosmetics Rules, 1945.
4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any device pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the device is marketed/sold or distributed. In such cases, action equivalent to that taken with reference to the concerned device in the country of origin or in the country of marketing shall be followed in India also, in consultation with and as per the directions of the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the device from Indian market.
5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in labelling or in testing, or in documentation of any of the device pertaining to this Registration Certificate. In such cases, where there shall be any major change/modification in manufacturing, or in testing, or in documentation as the case may be, the manufacturer or his authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub rule (3) of rule 24-A.
6. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and /or address of the registered office/ factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises.