



**Certificate No. 2780-12-2024-1**

**CERTIFICATE TO FOREIGN GOVERNMENT**

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(Two Pages)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer**

Dentium USA  
6761 Katella Ave.  
CYPRESS, CA USA 90630

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from December 19, 2024 to December 18, 2026.**



To verify the authenticity of the information on this certificate, you may scan the QR code or visit [www.access.fda.gov/fecv/CDRH](http://www.access.fda.gov/fecv/CDRH).



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**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2**

**Name of Manufacturer**

Dentium USA  
6761 Katella Ave.  
CYPRESS, CA  
USA 90630

**Name of Product(s)**

Endosseous Dental Implants

FXS3607BC: SuperLine II Fixture: 3.6 mm platform dia. - 7 mm length, cover screw included  
FXS3608C: SuperLine II Fixture: 3.6 mm platform dia. - 8 mm length, cover screw included  
FXS3610C: SuperLine II Fixture: 3.6 mm platform dia. - 10 mm length, cover screw included  
FXS3612C: SuperLine II Fixture: 3.6 mm platform dia. - 12 mm length, cover screw included  
FXS3614C: SuperLine II Fixture: 3.6 mm platform dia. - 14 mm length, cover screw included  
FXS4007BC: SuperLine II Fixture: 4.0 mm platform dia. - 7 mm length, cover screw included  
FXS4008C: SuperLine II Fixture: 4.0 mm platform dia. - 8 mm length, cover screw included  
FXS4010C: SuperLine II Fixture: 4.0 mm platform dia. - 10 mm length, cover screw included  
FXS4012C: SuperLine II Fixture: 4.0 mm platform dia. - 12 mm length, cover screw included  
FXS4014C: SuperLine II Fixture: 4.0 mm platform dia. - 14 mm length, cover screw included  
FXS4507BC: SuperLine II Fixture: 4.5 mm platform dia. - 7 mm length, cover screw included  
FXS4507C: SuperLine II Fixture: 4.5 mm platform dia. - 7 mm length with high collar, cover screw included  
FXS4508C: SuperLine II Fixture: 4.5 mm platform dia. - 8 mm length, cover screw included  
FXS4510C: SuperLine II Fixture: 4.5 mm platform dia. - 10 mm length, cover screw included  
FXS4512C: SuperLine II Fixture: 4.5 mm platform dia. - 12 mm length, cover screw included  
FXS4514C: SuperLine II Fixture: 4.5 mm platform dia. - 14 mm length, cover screw included  
FXS5007BC: SuperLine II Fixture: 5.0 mm platform dia. - 7 mm length, cover screw included  
FXS5007C: SuperLine II Fixture: 5.0 mm platform dia. - 7 mm length with high collar, cover screw included  
FXS5008C: SuperLine II Fixture: 5.0 mm platform dia. - 8 mm length, cover screw included  
FXS5010C: SuperLine II Fixture: 5.0 mm platform dia. - 10 mm length, cover screw included  
FXS5012C: SuperLine II Fixture: 5.0 mm platform dia. - 12 mm length, cover screw included  
FXS5014C: SuperLine II Fixture: 5.0 mm platform dia. - 14 mm length, cover screw included  
FXS6007C: SuperLine II Fixture: 6.0 mm platform dia. - 7 mm length with high collar, cover screw included  
FXS6008C: SuperLine II Fixture: 6.0 mm platform dia. - 8 mm length, cover screw included  
FXS6010C: SuperLine II Fixture: 6.0 mm platform dia. - 10 mm length, cover screw included  
FXS6012C: SuperLine II Fixture: 6.0 mm platform dia. - 12 mm length, cover screw included  
FXS7007C: SuperLine II Fixture: 7.0 mm platform dia. - 7 mm length with high collar, cover screw included  
FXS7008C: SuperLine II Fixture: 7.0 mm platform dia. - 8 mm length, cover screw included  
FXS7010C: SuperLine II Fixture: 7.0 mm platform dia. - 10 mm length, cover screw included  
FXS7012C: SuperLine II Fixture: 7.0 mm platform dia. - 12 mm length, cover screw included  
FX3608SWC: SuperLine Fixture: 3.6 mm platform dia. - 8 mm length, cover screw included  
FX3610SWC: SuperLine Fixture: 3.6 mm platform dia. - 10 mm length, cover screw included  
FX3612SWC: SuperLine Fixture: 3.6 mm platform dia. - 12 mm length, cover screw included  
FX3614SWC: SuperLine Fixture: 3.6 mm platform dia. - 14 mm length, cover screw included  
FX4008SWC: SuperLine Fixture: 4.0 mm platform dia. - 8 mm length, cover screw included  
FX4010SWC: SuperLine Fixture: 4.0 mm platform dia. - 10 mm length, cover screw included  
FX4012SWC: SuperLine Fixture: 4.0 mm platform dia. - 12 mm length, cover screw included  
FX4014SWC: SuperLine Fixture: 4.0 mm platform dia. - 14 mm length, cover screw included  
FX4508SWC: SuperLine Fixture: 4.5 mm platform dia. - 8 mm length, cover screw included  
FX4510SWC: SuperLine Fixture: 4.5 mm platform dia. - 10 mm length, cover screw included  
FX4512SWC: SuperLine Fixture: 4.5 mm platform dia. - 12 mm length, cover screw included  
FX4514SWC: SuperLine Fixture: 4.5 mm platform dia. - 14 mm length, cover screw included  
FX5008SWC: SuperLine Fixture: 5.0 mm platform dia. - 8 mm length, cover screw included  
FX5010SWC: SuperLine Fixture: 5.0 mm platform dia. - 10 mm length, cover screw included  
FX5012SWC: SuperLine Fixture: 5.0 mm platform dia. - 12 mm length, cover screw included  
FX5014SWC: SuperLine Fixture: 5.0 mm platform dia. - 14 mm length, cover screw included  
FX6008SWC: SuperLine Fixture: 6.0 mm platform dia. - 8 mm length, cover screw included  
FX6010SWC: SuperLine Fixture: 6.0 mm platform dia. - 10 mm length, cover screw included  
FX6012SWC: SuperLine Fixture: 6.0 mm platform dia. - 12 mm length, cover screw included  
FX7008SWC: SuperLine Fixture: 7.0 mm platform dia. - 8 mm length, cover screw included





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FX7010SWC: SuperLine Fixture: 7.0 mm platform dia. - 10 mm length, cover screw included  
FX7012SWC: SuperLine Fixture: 7.0 mm platform dia. - 12 mm length, cover screw included  
FX3408MLC: Implantium Fixture: 3.6 mm platform dia. - 8 mm length, cover screw included  
FX3410MLC: Implantium Fixture: 3.6 mm platform dia. - 10 mm length, cover screw included  
FX3412MLC: Implantium Fixture: 3.6 mm platform dia. - 12 mm length, cover screw included  
FX3414MLC: Implantium Fixture: 3.6 mm platform dia. - 14 mm length, cover screw included  
FX3808MLC: Implantium Fixture: 4.0 mm platform dia. - 8 mm length, cover screw included  
FX3810MLC: Implantium Fixture: 4.0 mm platform dia. - 10 mm length, cover screw included  
FX3812MLC: Implantium Fixture: 4.0 mm platform dia. - 12 mm length, cover screw included  
FX3814MLC: Implantium Fixture: 4.0 mm platform dia. - 14 mm length, cover screw included  
FX4308MLC: Implantium Fixture: 4.5 mm platform dia. - 8 mm length, cover screw included  
FX4310MLC: Implantium Fixture: 4.5 mm platform dia. - 10 mm length, cover screw included  
FX4312MLC: Implantium Fixture: 4.5 mm platform dia. - 12 mm length, cover screw included  
FX4314MLC: Implantium Fixture: 4.5 mm platform dia. - 14 mm length, cover screw included  
FX4808MLC: Implantium Fixture: 5.0 mm platform dia. - 8 mm length, cover screw included  
FX4810MLC: Implantium Fixture: 5.0 mm platform dia. - 10 mm length, cover screw included  
FX4812MLC: Implantium Fixture: 5.0 mm platform dia. - 12 mm length, cover screw included  
FX4814MLC: Implantium Fixture: 5.0 mm platform dia. - 14 mm length, cover screw included  
CS34: Cover Screw: 3.4 mm dia.  
CS36: Cover Screw: 3.6 mm dia.  
CS38: Cover Screw: 3.8 mm dia.

-----END OF PRODUCT LIST-----

