



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 10527-5-2018

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

(Three Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

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.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from May 15, 2018 to May 14, 2020.





U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR NEWER AND TECHNOLOGICAL PRODUCTS

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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Certificate No. 10527-5-2018

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

DENTALEZ, INC., STARDENTAL DIVISION
1816 Colonial Village Ln
LANCASTER, PA USA 17601

DENTALEZ OF ALABAMA
2500 U.S. HIGHWAY 31 SOUTH
BAY MINETTE, AL USA 36507

RAMVAC CORP.
212 N Main St
SPEARFISH, SD USA 57783

---END OF MANUFACTURER/DISTRIBUTOR LIST---





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3

Name of Manufacturer

DENTALEZ, INC., STARDENTAL DIVISION
1816 Colonial Village Ln
LANCASTER, PA USA 17601

Name of Product(s)

Simplicity High Speed Handpiece - 265633, 265634
Dental Instruments
430 Series High Speed Handpieces
264450, 264451, 262057, 264951, 262052, 264952, 264183, 261294,
261359, 265721, 268840, 268841, 265821, 265822, 266182, 266183,
266153, 266154, 268860, 268861, 265890, 265891, 265892, 265893
Solara Series High Speed Handpieces
265718, 265791, 265718Y, 265718F, 265718G, 265718B
Ceramic Bearing Turbines
263739, 263968, 264184, 263453, 265877, 265885
Steel Bearing Turbines
260296, 258661, 203111
Swivels
263758, 263772, 260152, 260144, 265400, 261547, 261550, 263773
268842, 268843, 259884, 263734, 265646
StarBright Quad Lamp Control
265330, 265331, 266166, 266169, 266170, 266172, 265677, 265676
Star E Torque Electric Handpiece System
265461, 265471, 265472, 265473, 265474, 265475, 265138
Concentrix Handpiece System
258739, 257629, 203048, 203098, 203099, 203103, 203108, 265630
Titan Low-Speed Motor Systems
Titan T Motor - 263940, 263941, 262292
TitanT Attachments - 263942, 263970, 263944, 263230
Titan T LubeFree Angles - 263950, 263948, 263954, 258953
Titan T Lubricated Angles - 263947, 261339
Titan 3 Motors - 262261, 262262, 262409, 262410, 262242, 262324,
262325, 265208
Titan 3 Attachments - 257506, 264073, 258443, 263230
Titan 3 LubeFree Angles - 264146, 262738, 262740, 265801, 264151
Titan 3 Lubricated Angles - 264182, 259005, 264149,
262570, 262571, 265803, 259008
Titan EX Motor System - 266105, 266107, 266100, 266101, 266102,
266103, 266134
Titan-E Motor - 266131, 266132
Prophy Star3 Hygiene Handpiece
264422, 262539
Restorative Kit - Titan 3
262583, 263972
Titan Blis-Sonic Scalars
264563, 264564, 264565, 202897, 261707, 260802, 261349, 256715,
256719, 256454, 264593, 260503, 265383, 265384, 265253, 265254,
261818, 261667, 261668, 261669, 263397, 263398, 263485, 263486,
264555, 264557, 264558, 264571, 263488, 264556, 261358, 264566
Classique Diamond Burs
Hand Instruments
Identafi Oral Cancer Screening System
RT3-00371, RT3-00372, RT3-00105, RT3-00415, RT3-00390
iStar Cordless Prophy Handpiece
265993, 265996

Name of Manufacturer





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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 3

DENTALEZ OF ALABAMA
2500 U.S. HIGHWAY 31 SOUTH
BAY MINETTE, AL USA 36507

Name of Product(s)

Dental Chair
J/V Generation Chair
3706-222C, 3706-223C, 3706-226C, 3706-227C, 3706-230C, 3706-231C,
3706-240C, 3706-262C
The Classic J-Chair
3706-174C, 3706-175C, 3706-188C, 3706-189C, 3703-202C, 3706-203C,
3706-234C
Nu-Simplicity Chair
3706-273C, 3706-274C, 3706-275C, 3706-276C
CORE
3706-284, 3706-284PT, 3706-285, 3706-285PT, 3706-285RW,
3706-285RWPT
Generation Stool
3554-198, 3554-198U, 3554-199, 3554-199U, 3554-200, 3554-200U,
3554-201, 3554-201U
Simplicity Stool
3554-202, 355-202U, 3554-203, 3554-203U
ErgoSure Stool
3554-204BL, 3554-204GR, 3554-205BL, 3554-205GR, 3625-786BL,
3625-786GR, 3625-787BL, 3625-787GR
Dental Light
Simplicity Light - 3544-117, 3544-178, 3544-187, 3544-189, 3544-207,
3544-191, 3544-192, 3544-202
everLight Operatory Light - 3544-195, 3544-196, 3544-197, 3544-198,
3544-199, 3544-200, 3544-201, 3544-205, 3544-206
CORE - 3544-223
Delivery Unit
Galaxy Wall & Cabinet Mounted Units - 3655-169
Simplicity Chair Mounted Unit - 3655-313, 3655-314G, 3655-313E
Simplicity Magellan Mounted Units - 3655-314, 3655-314G, 3655-314E,
3625-8278 assistant arms
Simplicity Hygiene Unit - 3655-284
CORE- 3655-358 Magellan, 3655-357 Console
NextGen Carts - 3636-129, 3636-130
Simplicity Carts - 3951-248, 3951-249

Name of Manufacturer

RAMVAC CORP.
212 N Main St
SPEARFISH, SD USA 57783

Name of Product(s)

Dental Vacuum System
Bulldog QT - 809E.0800.1, 809E.1050.1
Bison - 818E.0800.1, 818E.0800.3, 818E.1050.1, 818E.1050.3,
826E.0800.1, 826E.0800.3, 826E.1050.3
Badger - BADGLF1, BADGLF2
Tanks - 575015, 575030, 575080, 575085, 575580, 575585, 590053,
590050H
Water Ring Pumps
64586121, 64586221W, 645864122, 645864122W, 64586110D,
6458611DW, 64586211D, 6458621DW
SlugBuster Vacuum Cleaner





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Compressors

OSP22S, OSP22B, OSP13S, OSP13B, OSP23S, OSP23B, OSP24S,

OSP24B, OSP25S, OSP25B, OSP28S, OSP28B

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

