



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 14 0360 QS/NB/b

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 54/2015 (Collection of Laws), certifies that the product – medical devices of Class IIb

Dental Implants and Abutments

Brand name: DSI Implants™

manufactured by company

Dental Solutions Israel Ltd

9, Azriqam settlement, ZIP 79275, Israel

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803602225/2014, 803602328/2014 and 343603109/2015 which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.
2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **12th June 2019** at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:




RNDr. Radomír Čevelík

Issued in Zlín, on 13th July 2015

(This certificate replace withdraw certificate no. 14 0360 QS/NB/a issue on 23th October, 2014)

Representative of the Notified Body No. 1023



Annex to CERTIFICATE

No. 14 0360 QS/NB/b

Issued for the company:

Dental Solutions Israel Ltd

9, Azriqam settlement, ZIP 79275

Israel

List of the medical devices covered by the Certificate:

a) Dental implants

Cat. Number	Diameter	Shoulder	Description	Raw Material
SIG-F3308	3.30 mm	8.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3310	3.30 mm	10.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3311	3.30 mm	11.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3313	3.30 mm	13.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3316	3.30 mm	16.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3706	3.75 mm	6.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3708	3.75 mm	8.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3710	3.75 mm	10.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3711	3.75 mm	11.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3713	3.75 mm	13.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F3716	3.75 mm	16.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4206	4.20 mm	6.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4208	4.20 mm	8.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4210	4.20 mm	10.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4211	4.20 mm	11.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4213	4.20 mm	13.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4216	4.20 mm	16.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5006	5.00 mm	6.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5008	5.00 mm	8.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5010	5.00 mm	10.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5011	5.00 mm	11.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5013	5.00 mm	13.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5016	5.00 mm	16.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6006	6.00 mm	6.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6008	6.00 mm	8.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6010	6.00 mm	10.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6011	6.00 mm	11.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6013	6.00 mm	13.00 mm	«SDI» Spiral Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4306	4.20 mm	6.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4308	4.20 mm	8.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4310	4.20 mm	10.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4311	4.20 mm	11.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4313	4.20 mm	13.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F4316	4.20 mm	16.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5106	5.00 mm	6.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5108	5.00 mm	8.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5110	5.00 mm	10.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5111	5.00 mm	11.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5113	5.00 mm	13.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F5116	5.00 mm	16.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)

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RNDr. Radomír Čevellík
RNDr. Radomír Čevellík
Representative of the Notified Body No. 1023



Annex to CERTIFICATE

No. 14 0360 QS/NB/b

Issued for the company:

Dental Solutions Israel Ltd

9, Azriquam settlement, ZIP 79275

Israel

List of the medical devices covered by the Certificate:

SIG-F6106	6.00 mm	6.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6108	6.00 mm	8.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6110	6.00 mm	10.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6111	6.00 mm	11.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-F6113	6.00 mm	13.00 mm	«CSI» Spiral Cone Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3310	3.30 mm	10.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3311	3.30 mm	11.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3313	3.30 mm	13.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3316	3.30 mm	16.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3706	3.75 mm	6.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3708	3.75 mm	8.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3710	3.75 mm	10.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3711	3.75 mm	11.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3713	3.75 mm	13.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G3716	3.75 mm	16.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G4206	4.20 mm	6.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G4208	4.20 mm	8.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G4210	4.20 mm	10.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G4211	4.20 mm	11.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G4213	4.20 mm	13.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G4216	4.20 mm	16.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G5006	5.00 mm	6.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G5008	5.00 mm	8.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G5010	5.00 mm	10.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G5011	5.00 mm	11.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G5013	5.00 mm	13.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G5016	5.00 mm	16.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G6006	6.00 mm	6.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G6008	6.00 mm	8.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G6010	6.00 mm	10.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G6011	6.00 mm	11.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-G6013	6.00 mm	13.00 mm	«CDI» Cylindrical Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3010	3.00 mm	10.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3011	3.00 mm	11.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3013	3.00 mm	13.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3016	3.00 mm	16.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3310	3.30 mm	10.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3311	3.30 mm	11.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3313	3.30 mm	13.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3316	3.30 mm	16.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3710	3.75 mm	10.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3711	3.75 mm	11.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)

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Paul Voj
RNDr. Radomir Čevljk
Representative of the Notified Body No. 1023



Annex to CERTIFICATE

No. 14 0360 QS/NB/b

Issued for the company:

Dental Solutions Israel Ltd

9, Azriqam settlement, ZIP 79275

Israel

List of the medical devices covered by the Certificate:

SIG-P3713	3.75 mm	13.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-P3716	3.75 mm	16.00 mm	«OPI» One-Piece Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3308	3.30 mm	8.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3310	3.30 mm	10.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3311	3.30 mm	11.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3313	3.30 mm	13.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3316	3.30 mm	16.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3706	3.75 mm	6.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3708	3.75 mm	8.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3710	3.75 mm	10.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3711	3.75 mm	11.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3713	3.75 mm	13.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR3716	3.75 mm	16.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR4206	4.20 mm	6.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR4208	4.20 mm	8.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR4210	4.20 mm	10.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR4211	4.20 mm	11.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR4213	4.20 mm	13.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR4216	4.20 mm	16.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR5006	5.00 mm	6.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR5008	5.00 mm	8.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR5010	5.00 mm	10.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR5011	5.00 mm	11.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR5013	5.00 mm	13.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR5016	5.00 mm	16.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR6006	6.00 mm	6.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR6008	6.00 mm	8.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR6010	6.00 mm	10.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR6011	6.00 mm	11.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-IR6013	6.00 mm	13.00 mm	«MAI» Maintained Active Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3308	3.30 mm	8.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3310	3.30 mm	10.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3311	3.30 mm	11.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3313	3.30 mm	13.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3706	3.75 mm	6.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3708	3.75 mm	8.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3710	3.75 mm	10.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3711	3.75 mm	11.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI3713	3.75 mm	13.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI4206	4.20 mm	6.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI4208	4.20 mm	8.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI4210	4.20 mm	10.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)

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RNDr. Radomir Čevčík
RNDr. Radomir Čevčík
Representative of the Notified Body No. 1023



Annex to CERTIFICATE

No. 14 0360 QS/NB/b

Issued for the company:

Dental Solutions Israel Ltd

9, Azriqam settlement, ZIP 79275

Israel

List of the medical devices covered by the Certificate:

SIG-BI4211	4.20 mm	11.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI4213	4.20 mm	13.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI4216	4.20 mm	16.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI5006	5.00 mm	6.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI5008	5.00 mm	8.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI5010	5.00 mm	10.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI5011	5.00 mm	11.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI5013	5.00 mm	13.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI5016	5.00 mm	16.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI6006	6.00 mm	6.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI6008	6.00 mm	8.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI6010	6.00 mm	10.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI6011	6.00 mm	11.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BI6013	6.00 mm	13.00 mm	«BDI» Bio Dental Implant	Titanium Ti-6Al-4V (ASTM Grade 5)

b) Abutments

Cat. Number	Height	Shoulder	Description	Raw Material
SIG-A5602	10.50 mm	N/A	Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5908	8.50 mm	N/A	Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5909	9.50 mm	N/A	Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5911	11.5 mm	N/A	Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5912	12.5 mm	N/A	Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5509	9.50 mm	N/A	Straight, Wide, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5511	11.5 mm	N/A	Straight, Wide, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4801	8.50 mm	1.0 mm	Straight Shoulder Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4802	9.50 mm	2.0 mm	Straight Shoulder Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4803	10.50 mm	3.0 mm	Straight Shoulder Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4804	11.5 mm	4.0 mm	Straight Shoulder Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5300	8.50 mm	0.5 mm	Straight Shoulder Narrow Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5301	8.50 mm	1.5 mm	Straight Shoulder Narrow Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A5302	8.50 mm	2.5 mm	Straight Shoulder Narrow Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A6006	6.00 mm	N/A	Straight Narrow Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A6008	8.00 mm	N/A	Straight Narrow Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4601	9.00 mm	1.0 mm	Straight Anatomic Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4602	10.00 mm	2.0 mm	Straight Anatomic Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4603	11.00 mm	3.0 mm	Straight Anatomic Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A4604	12.00 mm	4.0 mm	Straight Anatomic Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3207	7.00 mm	N/A	15°, Standard Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2708	8.50 mm	N/A	15°, Standard Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3209	9.00 mm	N/A	15°, Standard Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3211	11.00 mm	N/A	15°, Standard Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2807	7.00 mm	N/A	15°, Narrow Top, Standard Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)

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Paul Voj
RNDr. Radomir Čevčík
Representative of the Notified Body No. 1023



Annex to CERTIFICATE

No. 14 0360 QS/NB/b

Issued for the company:

Dental Solutions Israel Ltd

9, Azriqam settlement, ZIP 79275

Israel

List of the medical devices covered by the Certificate:

SIG-A2809	9.00 mm	N/A	15°, Narrow Top, Standard Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2811	11.00 mm	N/A	15°, Narrow Top, Standard Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3609	9.00 mm	N/A	15°, Standard, Narrow Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2400	8.50 mm	0.8 mm	15°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2401	9.50 mm	1.0 mm	15°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2402	10.50 mm	2.0 mm	15°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2403	11.50 mm	3.0 mm	15°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2404	12.50 mm	4.0 mm	15°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3407	7.00 mm	N/A	25°, Standard, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3409	9.00 mm	N/A	25°, Standard, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3411	11.00 mm	N/A	25°, Standard, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3007	7.00 mm	N/A	25°, Standard, NT Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3009	9.00 mm	N/A	25°, Standard, NT Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3011	11.00 mm	N/A	25°, Standard, NT Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A3809	9.00 mm	N/A	25°, Standard, Narrow Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2601	9.50 mm	1.0 mm	25°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2602	10.50 mm	2.0 mm	25°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2603	11.50 mm	3.0 mm	25°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-A2604	12.50 mm	4.0 mm	25°, Anatomic, Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)

Cat. Number	Height	Shoulder	Description	Raw Material
SIG-T3001	N/A	N/A	Housing, for Internal Cap	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-T3002	N/A	N/A	Internal Cap, for 2.5mm Ball Attachment	Silicon - Extra Soft
SIG-T3003	N/A	N/A	Internal Cap, for 2.5mm Ball Attachment	Silicon - Soft
SIG-T3004	N/A	N/A	Internal Cap, for 2.5mm Ball Attachment	Silicon - Standard
SIG-T3005	N/A	N/A	Internal Cap, for 2.5mm Ball Attachment	Peek
SIG-T1201	N/A	1.0 mm	Straight Ball Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-T1202	N/A	2.0 mm	Straight Ball Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-T1203	N/A	3.0 mm	Straight Ball Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-T1204	N/A	4.0 mm	Straight Ball Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-T1205	N/A	5.0 mm	Straight Ball Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-T1206	N/A	6.0 mm	Straight Ball Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-M0101	1.0 mm	N/A	Multi-Unit Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-M0102	2.0 mm	N/A	Multi-Unit Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-M0103	3.0 mm	N/A	Multi-Unit Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-M0104	4.0 mm	N/A	Multi-Unit Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-M0105	5.0 mm	N/A	Multi-Unit Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-M0106	6.0 mm	N/A	Multi-Unit Straight Abutment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MT101	N/A	N/A	Multi-Unit, Titanium Sleeve	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MT10S	N/A	N/A	Multi-Unit, Short Titanium Sleeve	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-M0SC1	N/A	N/A	Screw for Multi-Unit	Titanium Ti-6Al-4V (ASTM Grade 5)

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Annex to CERTIFICATE

No. 14 0360 QS/NB/b

Issued for the company:

Dental Solutions Israel Ltd

9, Azriqam settlement, ZIP 79275

Israel

List of the medical devices covered by the Certificate:

SIG-PCA00	N/A	N/A	Straight Power Click Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PCA01	N/A	N/A	Straight Power Click Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PCA03	N/A	N/A	Straight Power Click Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PCA04	N/A	N/A	Straight Power Click Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PCA05	N/A	N/A	Straight Power Click Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PCMC0	N/A	N/A	Metal Cap for Power Click Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PCIA0	N/A	N/A	Indirect Peek Adaptor	Polyether Ether Ketone (PEEK)
SIG-PCPH0	N/A	N/A	Peek Housing for Power Click Attachment	Polyether Ether Ketone (PEEK)
SIG-PCSSR	N/A	N/A	Silicone Sealed Ring	Silicone Medical Tape
SIG-AA005	0.5 mm	N/A	Esthetic Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-AA010	2.0 mm	N/A	Esthetic Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-AA020	2.0 mm	N/A	Esthetic Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-AAS10	10.50 mm	N/A	Screw for Esthetic Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-AAS11	11.50 mm	N/A	Screw for Esthetic Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-AAS12	12.50 mm	N/A	Screw for Esthetic Attachment	Titanium Ti-6Al-4V (ASTM Grade 5)

Cat. Number	Height	Diameter	Description	Raw Material
SIG-MU09-1			9°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU09-2			9°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU09-3			9°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU18-1			18°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU18-2			18°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU18-3			18°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU30-1			30°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU30-2			30°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MU30-3			30°, Solid Angulated Multi Unit Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-VAC09-I	N/A	4.60 mm	9°, Versatile Angulated Connection Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-VAC18-I	N/A	4.60 mm	18°, Versatile Angulated Connection Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-VAC30-I	N/A	4.60 mm	30°, Versatile Angulated Connection Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC2-I	2.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC3-I	3.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC4-I	4.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC5-I	5.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC2-I	2.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC3-I	3.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC4-I	4.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC5-I	5.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PVAC2-I	2.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PVAC3-I	3.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PVAC4-I	4.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)

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Annex to CERTIFICATE

No. 14 0360 QS/NB/b

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9, Azriqam settlement, ZIP 79275

Israel

List of the medical devices covered by the Certificate:

SIG-PVAC5-I	5.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST05-I	0.5 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST1-I	2.0 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST2-I	3.0 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST3-I	4.0 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-VAC09-E	N/A	4.60 mm	9°, Versatile Angulated Connection Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-VAC18-E	N/A	4.60 mm	18°, Versatile Angulated Connection Base	Titanium Ti-6Al-4V (ASTM Grade 5)
	N/A	4.60 mm	30°, Versatile Angulated Connection Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-VAC30-E	N/A	4.60 mm	30°, Versatile Angulated Connection Base	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC2-E	2.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC3-E	3.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC4-E	4.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-BVAC5-E	5.0 mm	N/A	Ball Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC2-E	2.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC3-E	3.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC4-E	4.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-MVAC5-E	5.0 mm	N/A	Multi-Unit Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PVAC2-E	2.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PVAC3-E	3.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PVAC4-E	4.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-PVAC5-E	5.0 mm	N/A	Power Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST05-E	0.5 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST1-E	2.0 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST2-E	3.0 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)
SIG-EST3-E	4.0 mm	N/A	Esthetic Click Attachment For V.A.C.	Titanium Ti-6Al-4V (ASTM Grade 5)



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