

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**MIS Implants Technologies Ltd.
Bar Lev Industrial Park, 2015600
Israel**

for the scope

**dental implants, abutments, superstructures, drills, orthodontic screws, crest widener,
crown set (urethane oligomer based resin cement for implant retained crowns),
Bond Bone™ (resorbable dental bone graft), Power Tools
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex II – excluding Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2017-06-14
Valid until	2020-04-10
Registration no.	D1067100020
Report no.	P16-00995-99426
Stuttgart	2017-06-14



Head of Certification Body



Attachment of the certificate

No. D1067100020

Date 2017-06-14

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Product category	Product	Class	Product code
dental implants, abutments, superstructures, drills, orthodontic screws, crest widener, crown set (urethane oligomer based resin cement for implant retained crowns), Bond Bone™ (resorbable dental bone graft), Power Tools	superstructures (temporary superstructures)	Ila	GMDN:44880
	abutments (permanent)	Ila	GMDN:44879
	abutments (prosthetic screws)	Ila	GMDN:44879
	superstructures (analog respectively)	Ila	GMDN:46122
	Drills (reusable drill)	Ila	GMDN:45714
	Drills (single use drills)	Ila	GMDN:45697
	Drills (countersinks)	Ila	GMDN:16462
	Drills (concave sinus screw / convex compress screw / osteotomes)	Ila	GMDN:44887
	Drills (trephine burs)	Ila	GMDN:14147
	Drills (twist drills, long twist drills, bone profiler)	Ila	GMDN:32390
	Drills (bone mill)	Ila	GMDN:18129
	Crest Widener	Ila	GMDN:47635
	Crown set (urethane oligomer based resin cement for implant retained crowns)	Ila	GMDN:35870
	Power Tools	Ila	GMDN:43662
	dental implants, Long implants	Ilb	GMDN:55844
	orthodontic screws	Ilb	GMDN:46536
	BondBone™ (resorbable dental bone graft)	III	GMDN:16966



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