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

2hl

Head of Certification Body





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Attachment of the certificate

No. D1067100020

Date 2017-06-14

Page 1 of 1

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



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