# **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, LOCKiT abutment system (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 2019-08-28 Valid until 2020-04-10 Registration no. D1067100022 Report no. P19-00537-144762 Stuttgart 2019-08-28

Head of Certification Body





Internet: http://www.mdc-ce.de

#### Attachment of the certificate

No. D1067100022

Date 2019-08-28

Page 1 of 1

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, LOCKiT abutment system	Drills (trephine burs)	lla	GMDN:14147
	Drills (countersinks)	lla	GMDN:16462
	Drills (bone mill)	lla	GMDN:18129
	Drills (twist drills, long twist drills, bone profiler)	lla	GMDN:32390
	Crown set (urethane oligomer based resin cement for implant retained crowns)	lla	GMDN:35870
	Power Tools	lla	GMDN:43662
	abutments (prosthetic screws)	lla	GMDN:44879
	superstructures (temporary superstructures)	lla	GMDN:44880
	Drills (concave sinus screw / convex compress screw / osteotomes)	lla	GMDN:44887
	Drills (single use drills)	lla	GMDN:45697
	Drills (reusable drill)	lla	GMDN:45714
	superstructures (analog respectively)	lla	GMDN:46122
	Crest Widener	lla	GMDN:47635
	abutments (permanent)	IIb	GMDN:44879
	LOCKiT abutment system	IIb	GMDN:44879
	orthodontic screws	IIb	GMDN:46536
	dental implants, Long implants	IIb	GMDN:55844
	BondBone <sup>™</sup> (resorbable dental bone graft)	III	GMDN:16966



Head of Certification Body