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, Orthodontic screws, BondBone™ (resorbable dental bone graft), Abutments, Superstructures, Crown set (urethane oligomer based resin cement for implant retained crowns), Drills, Dental surgical procedure kit, Dental 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 2020-01-17 2024-04-10 D1067100025 P19-00084-137662 2020-01-17

Head of Certification Body





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Attachment of the certificate

No. D1067100025

Date 2020-01-17

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Product category	Product	Class	Product code
Dental implants, Orthodontic screws, BondBone™ (resorbable dental bone graft), Abutments, Superstructures, Crown set (urethane oligomer based resin cement for implant retained crowns), Drills, Dental surgical procedure kit, Dental tools	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
	Dental tools- Screwdriver	lla	GMDN:33968
	Crown set - cement for implant retained crowns	lla	GMDN:35870
	Dental tools - Power tools	lla	GMDN:43662
	Superstructures - permanent superstructures, prosthetic screws	lla	GMDN:44879
	Dental tools - Osteotomes	lla	GMDN:44887
	Dental surgical procedure kit	lla	GMDN:45147
	Dental tools - Drill extender	lla	GMDN:45320
	Dental tools - Tissue punch	lla	GMDN:45329
	Drills - single use drills	lla	GMDN:45697
	Drills - reusable drills	lla	GMDN:45714
	Abutments - permanent abutments, LOCKiT abutment system	llb	GMDN:44879
	Superstructures - temporary superstructures	llb	GMDN:44880
	Orthodontic screws	llb	GMDN:46536
	Dental implants, long implants	llb	GMDN:55844
	BondBone™ (resorbable dental bone graft)	Ш	GMDN:16966



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