EC DECLARATION OF CONFORMITY

We: "MIS Implants Technologies Ltd."
P.O.Box 7 Bar Lev Industrial Park 2015600, Israel
Tel: +972(0)49016800

Declare under our sole responsibility that the products:

Dental Instruments Kits – MG1 and MK type (See attached list of products)

meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them.

The products are intended to be used by licensed dentist, for treatment of patient in the clinic.
MIS instruments are intended to assist during dental implantation procedures in the bone of the upper or lower jaw arches and in the fabrication of prosthetic restoration.
The devices are classified in Class I according to Rule no.1 and Rule no.5 of Annex IX of the Medical Device Directive.

Conformity assessment was performed according to Annex VII of the Directive and applicable standards.

The authorized representative within the EU who has been empowered to enter into commitments in our behalf:

MIS Implants Technologies GmbH
Simeonscarre 2, 32423, Minden, Germany
Tel: + 49 5719727620, Fax: + 49 5719727691, Email: Service@mis-implants.de

This D.O.C is valid until: 10.04.2024

Date: 01.03.2020

Nili Heled Opper
Legal Counsel and Regulatory Affairs Manager

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Implants Technologies Ltd.

List of products

Catalog No.	Description	Class*	Product Group
MG1-K002	Guided kit for final drills	Class I	Instruments
MK-0001	Abutment holding system kit	Class I	Instruments
MK-0040	Prosthetic planning kit	Class I	Instruments
MK-0056	Scan post Int. Hexagon connection Kit	Class I	Scan posts
MK-0057	Scan post Conical connection Kit	Class I	Scan posts
MK-C101	Coni. con. abutment holding system kit	Class I	Instruments

* according to medical device Directive 93/42/EEC.