

EC DECLARATION OF CONFORMITY

We: "MIS Implants Technologies Ltd."

P.O.Box 7 Bar Lev Industrial Park 2015600, Israel

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Declare under our sole responsibility that the products:

Dental Implants Kits – MK type (See attached list of products)

Dental Drills Kits – MG1, MG and MK type (See attached list of products)

Dental Instruments Kits – MG 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 implants are intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacements to restore chewing function. The implants are classified in Class IIb according to Rule no.8 of Annex IX of the Medical Device Directive.

MIS dental drills are intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw, to prepare bone for placement of an implant. The drills are classified in Class IIa according to Rule no.6 of Annex IX of the Medical Device Directive.

MIS dental 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 instruments are classified in Class IIa according to Rule no.6 of Annex IX of the Medical Device Directive.

Conformity assessment was performed according to Annex II.3 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

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Notified Body: mdc medical device certification GmbH No. 0483

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<http://www.mdc-ce.de>

This D.O.C is valid until: 10.04.2024

Date: 01.03.2020



Nili Heled Opper

Legal Counsel and Regulatory Affairs Manager

List of products

| Catalog No. | Description | Class* | Product Group |
|-------------|---|-----------|----------------|
| MG1-K001 | Guided kit for conic. con. implant procedure | Class IIa | Drills |
| MG-K001 | MGUIDE set for Seven implant procedure | Class IIa | Drills |
| MG-K002 | MGUIDE kit for Seven implant procedure, narrow sleeve | Class IIa | Drills |
| MG-K003 | MGUIDE kit for universal pilot drills | Class IIa | Drills |
| MG-K004 | MGUIDE set for conic. con. implant procedure | Class IIa | Drills |
| MG-K005 | MGUIDE kit for conic. con. implant procedure, narrow sleeve | Class IIa | Drills |
| MG-KD01 | MGUIDE drills kit for Seven implant procedure | Class IIa | Drills |
| MG-KD04 | MGUIDE drills kit for conic. con. implant procedure | Class IIa | Drills |
| MG-KD06 | MGUIDE 16 mm drills kit for SEVEN implant procedure | Class IIa | Drills |
| MG-KD07 | MGUIDE 16 mm drills kit for conic. con. implant procedure | Class IIa | Drills |
| MG-KT01 | MGUIDE tools kit for int. hex. | Class IIa | Drills |
| MG-KT04 | MGUIDE tools kit for conic. con. implant | Class IIa | Instruments |
| MK-0002 | Osteotomes kit | Class IIa | Osteotomes |
| MK-0011 | Abrahami drill guide kit | Class IIa | Parallel pins |
| MK-0014 | The Basic surgical kit | Class IIa | Drills |
| MK-0016 | Mountless Basic Surgical Kit | Class IIa | Drills |
| MK-0020 | Bone compression kit | Class IIa | Drills |
| MK-0023 | Sinus lift osteotomes set | Class IIa | Osteotomes |
| MK-0024 | Convex osteotomes set | Class IIa | Osteotomes |
| MK-0026 | Abrahami drill guide kit | Class IIa | Parallel pins |
| MK-0035 | Advanced surgical kit | Class IIa | Drills |
| MK-0036 | UNO implant surgical kit | Class IIa | Drills |
| MK-0037 | Mountless delivery tools set | Class IIa | Instruments |
| MK-0039 | Prosthetic tools kit | Class IIa | Instruments |
| MK-0041 | SOS broken screw kit | Class IIa | Instruments |
| MK-0044 | Surgical Kit for tapered impl. procedure | Class IIa | Drills |
| MK-0045 | External hexagon surgical kit | Class IIa | Drills |
| MK-0046 | C1 introduction kit | Class IIb | Implants |
| MK-0049 | Lance int. hex. surgical kit | Class IIa | Drills |
| MK-0052 | V3 experience kit | Class IIb | Implants |
| MK-0055 | V3 introduction kit | Class IIb | Implants |
| MK-0058 | Long implants drilling set | Class IIa | Drills |
| MK-0059 | Bone profiler Int. Hex. kit | Class IIa | Drills |
| MK-0060 | Bone profiler conic. con. kit | Class IIa | Drills |
| MK-BC101 | Drill stopper kit for C1 implant, SP | Class IIa | Drill stoppers |
| MK-BH26 | Bone harvest kit | Class IIa | Drills |
| MK-BS001 | Drill stopper kit for Seven implant, SP | Class IIa | Drill stoppers |
| MK-CD01 | Conical Connection drill kit. | Class IIa | Drills |
| MK-CDS08 | Drill stopper kit for 8mm length C1 implant procedure | Class IIa | Drill stoppers |
| MK-CDS10 | Drill stopper kit for 10mm length C1 implant procedure | Class IIa | Drill stoppers |
| MK-CDS11 | Drill stopper kit for 11.5mm length C1 implant procedure | Class IIa | Drill stoppers |
| MK-CDS13 | Drill stopper kit for 13mm length C1 implant procedure | Class IIa | Drill stoppers |
| MK-EI48 | Surgical kit for Seven impl. system with ext. irr. drill | Class IIa | Drills |
| MK-LDSK | Lance Drill stoppers kit | Class IIa | Drill stoppers |
| MK-SD01 | SEVEN drill kit | Class IIa | Drills |
| MK-SDS06 | Drill stopper kit for 6mm length Seven implant procedure | Class IIa | Drill stoppers |

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

| Catalog No. | Description | Class* | Product Group |
|--------------------|---|---------------|----------------------|
| MK-SDS08 | Drill stopper kit for 8mm length Seven implant procedure | Class IIa | Drill stoppers |
| MK-SDS10 | Drill stopper kit for 10mm length Seven implant procedure | Class IIa | Drill stoppers |
| MK-SDS11 | Drill stopper kit for 11.5mm length Seven implant procedure | Class IIa | Drill stoppers |
| MK-SDS13 | Drill stopper kit for 13mm length Seven implant procedure | Class IIa | Drill stoppers |
| MK-T044 | Surgical Kit for tapered impl. procedure | Class IIa | Drills |
| MK-T048 | Surgical kit for SEVEN impl. system | Class IIa | Drills |
| MK-T051 | V3 Surgical kit | Class IIa | Drills |