

EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company

MIS Implants Technologies Ltd.

Bar Lev Industrial Park, 2015600
Israel

EU Authorized Representative: DS REP B.V., Signaalrood 55, 2718 SG Zoetermeer, Netherlands

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 14 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-02-09	Registration No.	D1067100028
Valid until:	2027-02-08	Evaluation Report No.	200063

Stuttgart, 2022-02-09


Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: Abutment holding kit

Risk class: IIa – not implantable
Basic-UDI-DI: 07290113994287LL

Product: Angulated abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113997974N3

Product: Angulated abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113997981MY

Product: Angulated abutments (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113997998NH

Product: Ball attachments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998001L2

Product: Ball attachments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998018LK

Product: Ball attachments (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998025LG

Product: Bars for restoration

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998032LD

Product: Body try in / depth probe

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998049LW

Product: Bone compression kit

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998056LT

Product: Bone mill drill

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998063LQ

Product: Bone profiler kit

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998070LM

Product: Broken screw retrievers (motor)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998087M6

Product: Broken screw thread forming tool

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998094M3

Product: Broken screw retrievers / Kit

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113999275MG

Product: Burn-out plastic cylinders with a screw (Internal hex.)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998117LN

Product: Burn-out plastic cylinders with a screw (Abutment level)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998124LK

Product: Cementing posts (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998179MC

Product: Cementing posts (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998186M9

Product: Cementing posts (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998193M6

Product: CoCr abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998209LU

Product: CoCr abutments (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998216LR

Product: Comfort caps/CPK

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998223LN

Product: CONNECT abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998674MT

Product: CONNECT insertion tools (motor)

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998698N9

Product: CONNECT superstructures (Abutment level, Metal)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998704MB

Product: CONNECT superstructures (Abutment level, Metal + Plastic)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998711M8

Product: CONNECT superstructures (Abutment level)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998728MR

Product: Countersink drill

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998735MN

Product: Cover screws (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113994249LC

Product: Cover screws (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113994270L3

Product: Cover screws (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113994263L6

Product: CPK (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998759N4

Product: CPK (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998766MZ

Product: Drills kit

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998827MU

Product: Drill stoppers

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998742MK

Product: Drill stoppers kit

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998810MB

Product: Equator kit (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998858N7

Product: Equator kit (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998865N4

Product: Equator kit (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998872MZ

Product: Esthetic abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998889NJ

Product: Esthetic abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998896NF

Product: Extractors

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998926MX

Product: EZ-base (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998933MU

Product: EZ-base (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998940MR

Product: Fixation pins and anchoring screws

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998964N7

Product: Gold abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998971N4

Product: Gold abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998988NM

Product: Healing caps (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998995NJ

Product: Healing caps (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113999008LP

Product: Healing caps (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113999015LL

Product: Implant insertion tools (manual)

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113994218KZ

Product: Implant insertion tools (motor)

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113994294LH

Product: Implants (Conical)

Intended purpose: Dental implants are intended to serve as an anchor for tooth replacement

Risk class: IIb - implantable

Basic-UDI-DI: 07290113994256L9

Product: Implants (Internal hex.)

Intended purpose: Dental implants are intended to serve as an anchor for tooth replacement

Risk class: IIb - implantable

Basic-UDI-DI: 07290113994195LE

Product: Implants (External hex.)

Intended purpose: Dental implants are intended to serve as an anchor for tooth replacement

Risk class: IIb - implantable

Basic-UDI-DI: 07290113994232KT

Product: Incisor abutments / Ti-base (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998902MH

Product: Incisor abutments / Ti-base (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998919N2

Product: Instruments / Kit

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113999282MD

Product: LOCKiT abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113999121LL

Product: LOCKiT abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113999138M5

Product: LOCKiT kits (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113999145M2

Product: LOCKiT kits (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113999152LX

Product: Marking drill

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113999169MG

Product: MGUIDE drill (marking drill)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998230LK

Product: MGUIDE drill (pilot drill)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998247M4

Product: MGUIDE drill (procedure drill)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998254LZ

Product: MGUIDE insertion tools (manual)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998261LW

Product: MGUIDE insertion tools (motor)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998278MF

Product: MGUIDE tissue punch (motor)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998308LX

Product: MULTIFIX guide strip&spare screws

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998315LU

Product: Multi-Unit abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998322LR

Product: Multi-Unit abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998339MA

Product: Multi-Unit abutments (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998346M7

Product: Multi-Unit superstructures (Abutment level)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998353M4

Product: Overdenture metal superstructure

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998360LZ

Product: Overdenture plastic superstructure

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998377MJ

Product: Overdenture superstructures set

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998384MF

Product: Paralel pins

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998391MC

Product: Pilot drill

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998407M2

Product: Position drill

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998452M7

Product: Procedure drill for Lance implant system

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998469MQ

Product: Prosthetic screws

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113994201KG

Product: Screwdrivers (motor)

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998537MG

Product: Step drill

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998568MT

Product: Surgical Kit

Risk class: IIa - not implantable
Basic-UDI-DI: 07290113998575MQ

Product: Temporary plastic abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113994324KZ

Product: Temporary plastic abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113994331KW

Product: Temporary titanium abutments (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998599N6

Product: Temporary titanium abutments (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998605M8

Product: Temporary titanium abutments (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998612M5

Product: Ti-base (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable
Basic-UDI-DI: 07290113998629MN

Product: Ti-base (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998636MK

Product: Ti-base (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998643MG

Product: Ti-blanks (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998650MD

Product: Ti-blanks (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998667MW

Product: Tissue punch (manual)

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998957NA

Product: Tissue punch (motor)

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113998476MM

Product: Transgingival abutments / CPK (Conical)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998582MM

Product: Transgingival abutments / CPK (Internal hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113998544MD

Product: Transgingival abutments / CPK (External hex.)

Intended purpose: Dental abutments and corresponding screws are intended for connecting a prosthetic construction or a dental superstructure to a dental implant

Risk class: IIb - implantable

Basic-UDI-DI: 07290113997936MT

Product: Trephine burs

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113999299MW

Product: Twist drill

Risk class: IIa - not implantable

Basic-UDI-DI: 07290113999305LY

Notes:

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.