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 (SRN: IL-MF-000033949)

MSDI Medical Systems and Devices International Ltd.

Derech Haifa 37, P.O. Box 25414
Kiryat Ata, 2822639
Israel

EU Authorized Representative: MedNet EC-REP IIb GmbH, Borkstraße 10, 48163 Münster, Germany
(AR-SRN: DE-AR-000011192)

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III 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 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-12-22	Registration No.	D1441800006
Valid until:	2028-05-03	Evaluation Report No.	P23-01514-284323

Stuttgart, 2023-12-22

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:
Dental implants:
Alef Implant
Til Implant
Conix Implant

Intended purpose:
surgical restorative application for placement in the bone of the upper and lower jaw, to provide support of prosthetic devices, such as artificial teeth.

Risk class: IIb

Product:
Anatomic and healing abutments

Intended purpose:
to be used in conjunction with endosseous dental implants fixture to aid in prosthetic rehabilitation.

Risk class: IIb

Product:
Straight abutments
Angled abutments

Intended purpose:
to be used in conjunction with endosseous dental implants fixture to aid in prosthetic rehabilitation, designed for both single tooth and bridges (more than one tooth).

Risk class: IIb

Product:
Standard multi-unit abutments and multi-unit kits
Angled multi-unit abutments

Intended purpose:
to be used to support multiple tooth prosthesis in the mandible or maxilla.

Risk class: IIb

Product:
Temporary abutments

Intended purpose:
to establish tooth and gingival contours

Risk class: IIb

Product:
Ball attachments and ball attachment kits
Lock attachments and lock attachment kits

Intended purpose:
to retain an overdenture or partial prosthesis to a series of dental implants placed along the jaw

Risk class: IIb

Product:
Healing caps

Intended purpose:
to be used with the implant system to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process

Risk class: IIb

Product:
Cover screws

Intended purpose:
to be used with the implant system to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Risk class: IIb

Product:
Ti base abutments

Intended purpose:
to overcome issues related to existing abutments, such as the unaesthetic appearance of titanium abutments and the low fracture strength of ceramic abutments.

Risk class: IIb

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.