EU Quality Management System Certificate

We hereby certify the company

Adin Dental Implant Systems Ltd.
Industrial Zone Alon Tavor, POB 1128
Afula 1811101
Israel

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets 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 from mdc medical device certification GmbH (Notified Body 0483) consists of 4 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-02-17	Registration No.	D1437500007
Valid until	2028-11-09	Report No.	P25-00577-332986

Stuttgart, 2026-02-17

Notified Body

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

EU Authorized Representative:

MedNet EC-Rep GmbH
Borkstraße 10,
48163 Münster
Germany
DE-AR-000000002

Devices:

Dental Implants:
Touareg™ dental implants
Touareg™-S dental implants
Touareg™-OS dental implants
Touareg CloseFit dental implants
Touareg UniFit dental implants
Swell™ dental implants
Triple™ dental implants
One™ dental implants

Intended purpose: Adin's dental implants and abutments are intended to be used in conjunction with each other during implant surgical placement in the maxillary and/or mandibular arches to support single-unit or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

Risk class: IIb

Abutments:
Healing Abutments
Cement Retained Abutments
Screw Retained Abutments
Cement or Screw Retained Abutments (UCLA Abutments)
Prosthetic Components for CAD/CAM (TMA cementing cone, Ti base, Ti blank)
Overdenture Attachments (Ball Attachment, Grip attachments)
Abutment Screws
Implant’s Cover Screws

Intended purpose: Adin's dental implants and abutments are intended to be used in conjunction with each other during implant surgical placement in the maxillary and/or mandibular arches to support single-unit or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

Risk class: IIb

Zygomatic Dental Implants:
Touareg™-OS Zygomatic Dental Implants

Intended purpose: Adin's Touareg™-OS Zygomatic Dental Implants are intended for Surgical placement through the maxillary arch and anchored in the zygomatic bone to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function in edentulous or partially edentulous patients only with severe atrophic maxilla.
Immediate loading (function) is applicable provided that stability requirements are satisfied.

Risk class: IIb

Zygomatic Dental Drills

Risk class: IIa

Freehand Surgery Drills

Risk class: IIa

Freehand Surgery Handpiece Connected Tools

Risk class: IIa

Guided Surgery Drills

Risk class: IIa

Guided Surgery Handpiece Connected Tools

Risk class: IIa

Anchorage Screws

Risk class: IIa

Osteotomes

Risk class: I (reusable)

Guided Surgery Tissue Punches

Risk class: IIa

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.

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.

The certificate is based on the previous certificate

D1437500005 (2023-11-10)
D1437500006 (2024-06-24)

with the following changes to D1437500006:
Regarding product group Zygomatic Dental Implants:
Intended use was updated to reflect current clinical practice