

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 product:

Crown Set – MK-0022

Meets the provisions of the Council Directive 93/42/EEC, amended MDD 2007/47/EC, concerning medical devices which apply to them.

The product is intended for long-term cementation for permanent implant-retained restorations and long-term provisionals.

The device is classified in Class IIa according to Rule no.8 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

Simeonscarre 2, 32423, Minden, Germany

Tel: + 49 5719727620, Fax: + 49 5719727691, Email: Service@mis-implants.de

Notified Body: mdc medical device certification GmbH No. 0483

Kriegerstrasse 6

D-70191 Stuttgart, Germany,

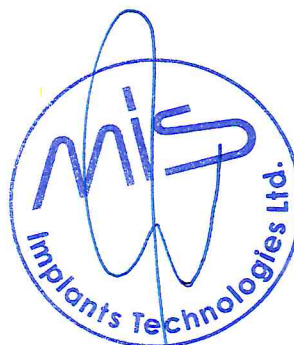
Phone: +49-(0)711-253597-0

Fax: +49-(0)711-253597-10

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

This D.O.C is valid until: 30.04.2019

Date: 30.04.2017



Nili Heled Oppen
Legal Counsel and Regulatory Affairs Manager
