EC DECLARATION OF CONFORMITY

We: "MIS Implants Technologies Ltd."
P.O.Box 7 Bar Lev Industrial Park 2015600, Israel
Tel: +972-4-9016800 Fax: +972-4-9918623

Declare under our sole responsibility that the product Orthodontic Anchor Screws under catalog number MG2 (see attached list of products)

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

The product(s) is (are) intended to be used by licensed dentist, for treatment of patient in the clinic.
The product(s) is (are) intended to provide a variety of clinical solutions, including reconstruction of single tooth, screw – retained or cemented fixed bridges and over-dentures.

The devices are classified in Class IIb 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
Postfach 1651, 32376 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: 20.03.2016

Date: 20.03.2014

MIS Implants Technologies LTD

Shmaya David
QA & RA Manager

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List of products

Cat. Num.	Description
MG2-06160	Ortho anchor screw diameter 1.60 L 6mm
MG2-08160	Ortho anchor screw diameter 1.60 L 8mm
MG2-10160	Ortho anchor screw diameter 1.60 L 10mm
MG2-12160	Ortho anchor screw diameter 1.60 L 12mm