CERTIFICATE

This is to certify that the company

MIS Implants Technologies Ltd.

Bar Lev Industrial Park 2015600
Israel

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certificate and applicable country-specific requirements:
Design, manufacturing and distribution of Dental Implants, Dental Instruments, Superstructures, Drills, Orthodontic Screws, Crest Widener and Resorbable Dental Bone Graft, Crown Set, Custom made surgical guides, Custom made CAD/CAM abutments, crowns and brigdes.
-**AUS (a), BRA, CND, JPN, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope
(full references are listed in the annex)

Certificate registration no.	309322 MDSAP16
Certificate unique ID	170701104
Effective date	2018-03-09
Expiry date	2021-03-08
Frankfurt am Main	2018-03-08

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

Annex to certificate
Certificate registration No.: 309322 MDSAP16
Certificate unique ID: 170701104
Effective date: 2018-03-08

MIS Implants Technologies Ltd.

Bar Lev Industrial Park 2015600
Israel

Site	Scope
MIS Implants Technologies Ltd. Bar Lev Industrial Park 2015600 Israel	Design, manufacturing and distribution of Dental Implants, Dental Instruments, Superstructures, Drills, Orthodontic Screws, Crest Widener and Resorbable Dental Bone Graft, Crown Set, Custom made surgical guides, Custom made CAD/CAM abutments, crowns and brigdes. -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **DUNS No. 514576057**

Annex to certificate
Certificate registration No.: 309322 MDSAP16
Certificate unique ID: 170701104
Effective date: 2018-03-08

MIS Implants Technologies Ltd.

Bar Lev Industrial Park 2015600
Israel

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821