



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 certification:

Design, manufacturing and distribution of Dental Implants, Dental Instruments, Superstructures, Drills, Orthodontic Screws, Resorbable Dental Bone Graft, Crown Set, Custom made surgical guides.

-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

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	309322 MDSAP16
Certificate unique ID	170776318
Effective date	2021-12-04
Expiry date	2024-12-03
Frankfurt am Main	2021-12-04



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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.



Annex to certificate
Certificate registration No.: 309322 MDSAP16
Certificate unique ID: 170776318
Effective date: 2021-12-04



MIS Implants Technologies Ltd.

Bar Lev Industrial Park 2015600
Israel

Audited site

REPs FEI No.: site scope and country-specific requirements

546908
MIS Implants Technologies Ltd.
Bar Lev Industrial Park 2015600
Israel

Design, manufacturing and distribution of Dental Implants, Dental Instruments, Superstructures, Drills, Orthodontic Screws, Resorbable Dental Bone Graft, Crown Set, Custom made surgical guides.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)
REPs FEI No.: F000659

546909
MIS Implants Technologies Ltd.
Bar Lev Industrial Park (west) 2015600
Israel

Design, manufacturing and distribution of Dental Implants, Dental Instruments, Superstructures, Drills, Orthodontic Screws, Resorbable Dental Bone Graft, Crown Set, Custom made surgical guides.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)
REPs FEI No.: F000659



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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