

## ***EC DECLARATION OF CONFORMITY***

***We: "Medical Systems and Devices International Ltd."***

Derech Haifa 37, Kiryat Ata, 2822639, P.O Box 25414, Israel.

Tel: 972-054-932-0515

***Declare under our sole responsibility that the following products listed in Appendix 1 meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, which apply to them.***

***The devices are intended to be used by licensed dentist, for treatment of patient in the clinics.***

***The devices (Dental accessories) with the Basic UDI-DI 7290018434ACC4S are classified as Class I according to Rule 5 of Annex VIII of the Regulation (EU) 2017/745, and are listed in Appendix 1.***

***The devices (Dental tools) with the Basic UDI-DI 7290018434INS83 are classified as Class I according to Rule 5 of Annex VIII of the Regulation (EU) 2017/745, and are listed in Appendix 1.***

***The Conformity assessment route is Annex II and Annex III of the Regulation (EU) 2017/745.***

***Conformity assessment is based on a quality management system and on assessment of technical documentation as well as the list of standards as described in Appendix 2.***

***GMDN Codes: 65191, 61642, 61640, 61647, 64312, 61641, 44901, 33968, 47829***

***The authorized representative within the EU who has been empowered to enter into commitments on our behalf is:***

***MedNet EC-REP I Ib GmbH***

***Borkstrasse 10, 48163 Münster, Germany***


***SRN: DE-AR-000011192***



This DOC is valid till 10/12/2028

Date: 10/12/2023

Place of issue of the declaration: Kiryat Ata, Israel.

  
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Omri Elgerabli, CEO

## Appendix 1: List of products

### Accessories

Cat. No	Description	Basic UDI-DI
MUTS	Multi-unit titanium sleeve	7290018434ACC4S
MUPS	Multi-unit plastic sleeve	7290018434ACC4S
MUHR	Multi-unit angled holder	7290018434ACC4S
MUTB	Multi-unit Ti base	7290018434ACC4S
MUSC	Multi-unit screw	7290018434ACC4S
BACAP	Ball silicon cap	7290018434ACC4S
LOCKMH	Lock metal housing	7290018434ACC4S
BAMH	Ball metal housing	7290018434ACC4S
NPMUAC	Multi-unit adhesive coping NP	7290018434ACC4S
LOCKES	Silicon cap yellow extra soft retention	7290018434ACC4S
LOCKSO	Silicon cap pink soft retention	7290018434ACC4S
LOCKST	Silicon cap clear standard retention	7290018434ACC4S
LOCKRI	Silicon ring	7290018434ACC4S
LOCKSG	Silicon cap purple strong retention	7290018434ACC4S
CANR	Castable abutment non rotational	7290018434ACC4S
CAR	Castable abutment rotational	7290018434ACC4S
CATB	Castable abutment with titanium base	7290018434ACC4S
ALAS	Abutment screw	7290018434ACC4S
TPCAR	Castable abutment TP rotational	7290018434ACC4S
TPAS	Abutment screw TP	7290018434ACC4S
RPCANR	Castable abutment RP non rotational	7290018434ACC4S
RPAS	Abutment screw RP	7290018434ACC4S
NPCANR	Castable abutment NP non rotational	7290018434ACC4S
CA15NR1	Angled castable abutment with shoulder 1mm - 15°	7290018434ACC4S
CA15NR2	Angled castable abutment with shoulder 2mm - 15°	7290018434ACC4S
CA15NR3	Angled castable abutment with shoulder 3mm - 15°	7290018434ACC4S
CA25NR1	Angled castable abutment with shoulder 1mm - 25°	7290018434ACC4S
CA25NR2	Angled castable abutment with shoulder 2mm - 25°	7290018434ACC4S
CA25NR3	Angled castable abutment with shoulder 3mm - 25°	7290018434ACC4S
CANR1	Castable abutment non rotational 1mm	7290018434ACC4S
CANR2	Castable abutment non rotational 2mm	7290018434ACC4S
CANR3	Castable abutment non rotational 3mm	7290018434ACC4S
NPAS	Abutment screw NP	7290018434ACC4S
ANS	Analog standard	7290018434ACC4S
ANW	Analog wide	7290018434ACC4S
TROS	Transfer open tray short 9mm	7290018434ACC4S
TROL	Transfer open tray long 13mm	7290018434ACC4S
TRC	Transfer closed tray 9mm	7290018434ACC4S
TRKS	Transfer click short 9mm	7290018434ACC4S
TRKL	Transfer click long 13mm	7290018434ACC4S
TRWOL	Transfer open tray wide long 13mm	7290018434ACC4S
SOTR1	Snap on transfer 1mm	7290018434ACC4S
SOTR2	Snap on transfer 2mm	7290018434ACC4S
SOTR3	Snap on transfer 3mm	7290018434ACC4S
SOTR4	Snap on transfer 4mm	7290018434ACC4S
SOC	Snap on Cap	7290018434ACC4S
MUTR	Multi-unit transfer	7290018434ACC4S

MUAN	Multi-unit analog	7290018434ACC4S
MUTRS	Multi-unit transfer screw	7290018434ACC4S
MUAC	Multi-unit adhesive coping	7290018434ACC4S
TPAN	Analog TP	7290018434ACC4S
TPTRC	Transfer TP closed tray	7290018434ACC4S
TPTRO	Transfer TP open tray	7290018434ACC4S
TPMUAC	Multi-unit adhesive coping TP	7290018434ACC4S
RPAN	Analog RP	7290018434ACC4S
RPTRO	Transfer RP open tray	7290018434ACC4S
RPTRC	Transfer RP closed tray	7290018434ACC4S
RPMUAC	Multi-unit adhesive coping RP	7290018434ACC4S
NPAN	Analog NP	7290018434ACC4S
NPTRC	Transfer NP closed tray	7290018434ACC4S
NPTRC	Transfer NP closed tray	7290018434ACC4S
WTROS	Transfer open tray short wide	7290018434ACC4S
WTROL	Transfer open tray long wide 13mm	7290018434ACC4S

### Tools

Cat. No	Description	Basic UDI-DI
MUSB	Multi-unit scan body	7290018434INS83
MUDA	Multi-unit digital analog	7290018434INS83
SB7	Scan body 7mm	7290018434INS83
SB9	Scan body 9mm	7290018434INS83
DAN	Digital analog	7290018434INS83
AN	Digital analog TP	7290018434INS83
TPSB7	Scan body TP 7mm	7290018434INS83
TPSB9	Scan body TP 9mm	7290018434INS83
RPDAN	Digital analog RP	7290018434INS83
RPSB	Scan body RP	7290018434INS83
NPDAN	Digital analog NP	7290018434INS83
NPSB	Scan body NP	7290018434INS83
RPSB7	Scan Body RP 9mm	7290018434INS83
RPSB9	Scan Body RP 7mm	7290018434INS83
NPSB7	Scan Body NP 9mm	7290018434INS83
NPSB9	Scan Body NP 7mm	7290018434INS83
NPDMIL	Implant Drivers For Motor NP long 28mm	7290018434INS83
NPDMIS	Implant Drivers For Motor NP short 22mm	7290018434INS83
DRPS	Driver ratchet prosthetics short 10mm	7290018434INS83
DRPL	Driver ratchet prosthetics long 15mm	7290018434INS83
DRIMS	Driver ratchet implants short 10mm	7290018434INS83
DRIML	Driver ratchet implants long 15mm	7290018434INS83
DMS	Driver manual short 10mm	7290018434INS83
DML	Driver manual long 15mm	7290018434INS83
RACT	Ratchet Wrench	7290018434INS83
RATQ	Torque Wrench	7290018434INS83
DPTH	Depth Probe	7290018434INS83
SSIM	Screwdriver for implant	7290018434INS83
SSID	Screwdriver for implant driver	7290018434INS83
DMIL	Implant Drivers For Motor long 28mm	7290018434INS83



DMIS	Implant Drivers For Motor short 22mm	7290018434INS83
DMPL	Prosthetics driver for motor long 28mm	7290018434INS83
DMPS	Prosthetics driver for motor short 22mm	7290018434INS83
TPDRIMS	Driver ratchet implant TP short 10mm	7290018434INS83
TPDRIML	Driver ratchet implant TP long 15mm	7290018434INS83
TPDMIL	Implant Drivers For Motor TP long 28mm	7290018434INS83
TPDMIS	Implant Drivers For Motor TP short 22mm	7290018434INS83
RPDRIML	Driver ratchet implant RP short 10mm	7290018434INS83
RPDRIMS	Driver ratchet implant RP long 15mm	7290018434INS83
RPDMIL	Implant Drivers For Motor RP long 28mm	7290018434INS83
RPDMIS	Implant Drivers For Motor RP short 22mm	7290018434INS83
NPDRIMS	Driver ratchet implant NP short 10mm	7290018434INS83
NPDRIML	Driver ratchet implant NP long 15mm	7290018434INS83
PDGS	Parallel depth guide short 10mm	7290018434INS83
PDGL	Parallel depth guide long 18mm	7290018434INS83
BATL	Ball insertion tool	7290018434INS83
MCDS	AL Motor mount Click Driver short	7290018434INS83
MCDL	AL Motor mount Click Driver long	7290018434INS83
TPMCDS	TP Motor mount Click Driver short	7290018434INS83
TPMCDL	TP Motor mount Click Driver long	7290018434INS83
NPMCDS	NP Motor mount Click Driver short	7290018434INS83
NPMCDL	NP Motor mount Click Driver Long	7290018434INS83
RPMCDS	RP Motor mount Click Driver Short	7290018434INS83
RPMCDL	RP Motor mount Click Driver Long	7290018434INS83
RCDS	AL Ratchet Click Driver Short	7290018434INS83
RCDL	AL Ratchet Click Driver Long	7290018434INS83
TPRCDS	TP Ratchet Click Driver Short	7290018434INS83
TPRDCL	TP Ratchet Click Driver Long	7290018434INS83
NPRCDS	NP Ratchet Click Driver Short	7290018434INS83
NPRCDL	NP Ratchet Click Driver Long	7290018434INS83
RPRCDS	RP Ratchet Click Driver Short	7290018434INS83
RPRCDL	RP Ratchet Click Driver Long	7290018434INS83
IHDS	AL Implant Hand Driver Short	7290018434INS83
IHDL	AL Implant Hand Driver Long	7290018434INS83
TPIHDS	TP Implant Hand Driver Short	7290018434INS83
TPIHDL	TP Implant Hand Driver Long	7290018434INS83
NPIHDS	NP Implant Hand Driver Short	7290018434INS83
NPIHDL	NP Implant Hand Driver Long	7290018434INS83
RPIHDS	RP Implant Hand Driver Short	7290018434INS83
RPIHDL	RP Implant Hand Driver Long	7290018434INS83

## Appendix 2: List of Applicable Standards

#	Standard number	Standard description
1.	EU MDR 2017/745	Medical Devices Regulation (MDR) (EU) 2017/745
2.	TITLE 21- Part 820	Food and drugs Chapter I-- Food and drug administration Department of Health and Human Services Subchapter H – Medical Devices
3.	EN ISO 13485:2016	Quality Systems-Medical Devices-System requirements for regulatory purposes
4.	EN ISO 10993-1:2020	Biological evaluation of medical devices. Part 1: Evaluation and testing
5.	EN ISO 14971:2019	Medical Devices-Application of risk management to medical devices within a risk management process
6.	EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied
7.	BS EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
8.	ASTM F 136-13	Standard specification for wrought Titanium-6 Aluminium-4 Vanadium ELI (extra low interstitial) alloy for surgical implant applications (UNS R56401)
9.	BS EN ISO 5832-3:2012	Implants for surgery – Metallic materials – Wrought titanium 6- aluminium 4-vanadium alloy
10.	BS EN ISO 5832:3-2012	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
11.	ISO 17665-2:2009	Sterilization of health care products - moist heat - part 2: guidance on the application of ISO 17665-1
12.	BS EN ISO 17664:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
13.	BS EN ISO 17665-1:2016	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
14.	EN 62366-1:2015/Amd 1:2020	Medical devices - application of usability engineering to medical devices

#	Guidance Number	Guidance Description
1.	MEDDEV 2.12/1 rev.8	Guidelines on a medical devices vigilance system
2.	MDCG 2021-24, Oct.2021	Guidance on classification of medical devices
3.	MEDDEV 2.7/1 rev. 4	Clinical evaluation: A guide for manufacturers and Notified Bodies
4.	MDCG 2019-15 rev.1, Dec.2019	Guidance notes for manufacturers of class I medical devices
5.	MDCG 2020-5, April 2020	Clinical Evaluation – Equivalence (April 2020)
6.	MDCG 2020-13 July 2020	Clinical evaluation assessment report template

7.	MDCG 2020-6, April 2020	Background note on the relationship between MDCG 2020-6 and MEDDEV 2.7/1 rev.4 on clinical evaluation
8.	MDCG 2020-5, April 2020	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
9.	MDCG 2020-13, July 2020	Clinical evaluation assessment report template (July 2020)
10.	MDCG 2021-19, July 2021	Guidance note integration of the UDI within an organisation's quality management system
11.	MDCG 2018-1, April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
12.	MDCG 2023-3, Feb.2023	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices