EC DECLARATION OF CONFORMITY

We: "MSDI Medical Systems and Devices International Ltd."
Derech Haifa 37, Kiryat Ata, 2822639, P.O Box 25414, Israel
Tel: 972-054-932-0515
SRN Number: IL-MF-000033949

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 Code: 55847

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

MedNet EC-REP IIb GmbH
Borkstrasse 10, 48163 Münster, Germany
SRN: DE-AR-000011192

CE

This DOC is valid till 2031-10-26
Date: 2026-10-26

Place of issue of the declaration: Kiryat Ata, Israel

Omri Elgerabli, CEO

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Appendix 1: List of products

Accessories

Cat. No	Description	Basic UDI-DI
MUTS	Multi-unit titanium sleeve	7290018434ACC4S
MUPS	Multi-unit plastic sleeve	7290018434ACC4S
MUSB	Multi-unit scan body	7290018434ACC4S
1.4MUSB	Multi-unit 1.4 Scan body	7290018434ACC4S
MUSB9	Multi-unit scan body 9mm	7290018434ACC4S
MUDA	Multi-unit digital analog	7290018434ACC4S
1.4MUDA	Multi-unit 1.4 Digital analog	7290018434ACC4S
SB7	Scan body 7mm	7290018434ACC4S
SB9	Scan body 9mm	7290018434ACC4S
SB12	Scan Body 12mm	7290018434ACC4S
DAN	Digital analog	7290018434ACC4S
MUANNR	Multi-Unit Analog Non Rotational	7290018434ACC4S
MUTRNR	Multi-unit transfer Non Rotational	7290018434ACC4S
MUPSNR	Multi-unit plastic sleeve Non Rotational	7290018434ACC4S
MUSBNR	Multi-unit scan body Non Rotational	7290018434ACC4S
MUDANNR	Multi-unit digital analog non rotational	7290018434ACC4S
GDS43	Guided Ti Sleeve 4.3mm	7290018434ACC4S
MUSC	Multi-unit screw	7290018434ACC4S
1.4MUSC	Multi-Unit 1.4 Screw	7290018434ACC4S
MUASC	Multi-unit angled abutment screw	7290018434ACC4S
BACAP	Ball silicon cap	7290018434ACC4S
LOCKMH	Lock metal housing	7290018434ACC4S
BAMH	Ball metal housing	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
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
RPDAN	Digital analog RP	7290018434ACC4S
NPDAN	Digital analog NP	7290018434ACC4S
RPSB7	Scan Body RP 7mm	7290018434ACC4S
RPSB9	Scan Body RP 9mm	7290018434ACC4S
NPSB7	Scan Body NP 7mm	7290018434ACC4S
NPSB9	Scan Body NP 9mm	7290018434ACC4S
BXSC15	Biaxial screw 7.9 mm	7290018434ACC4S
BXSC30	Biaxial screw 9.4 mm	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
SOC	Snap on Cap	7290018434ACC4S
MUTR	Multi-unit transfer	7290018434ACC4S
1.4MUTR	Multi-Unit transfer 1.4	7290018434ACC4S
MUAN	Multi-unit analog	7290018434ACC4S
1.4MUAN	Multi-Unit Analog 1.4	7290018434ACC4S
MUTRS	Multi-unit transfer screw	7290018434ACC4S
1.4MUTRS	Multi-Unit 1.4 transfer screw	7290018434ACC4S
TPAN	Analog TP	7290018434ACC4S
TPDAN	Digital analog TP	7290018434ACC4S
TPSB7	Scan body TP 7mm	7290018434ACC4S
TPSB9	Scan body TP 9mm	7290018434ACC4S
TPSB12	Scan Body TP 12mm	7290018434ACC4S
TPBXSC15	Biaxial screw 7.9 mm TP	7290018434ACC4S
TPBXSC30	Biaxial screw 9.4 mm TP	7290018434ACC4S
TPTRC	Transfer TP closed tray	7290018434ACC4S
TPTRO	Transfer TP open tray	7290018434ACC4S
RPAN	Analog RP	7290018434ACC4S
RPTRO	Transfer RP open tray	7290018434ACC4S
RPTRC	Transfer RP closed tray	7290018434ACC4S
NPAN	Analog NP	7290018434ACC4S
NPTRO	Transfer NP open tray	7290018434ACC4S
NPTRC	Transfer NP closed tray	7290018434ACC4S
WTROS	Transfer open tray short wide	7290018434ACC4S
WTROL	Transfer open tray long wide13mm	7290018434ACC4S

Tools

Cat. No	Description	Basic UDI-DI
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

RATQAD	Torque wrench square adaptor	7290018434INS83
RATQ	Torque Wrench	7290018434INS83
DPTH	Depth Probe	7290018434INS83
SSIM	Screwdriver for implant	7290018434INS83
SSID	Screwdriver for implant driver	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 long15mm	7290018434INS83
PDGS	Parallel depth guide short 10mm	7290018434INS83
PDGL	Parallel depth guide long 18mm	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
RCDS7	AL Ratchet Click Driver Short 7mm	7290018434INS83
RCDL	AL Ratchet Click Driver Long	7290018434INS83
TPRCDS	TP Ratchet Click Driver Short	7290018434INS83
TPRCDL	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
BXMDRS	Biaxial motor driver short 24.5 mm	7290018434INS83
BXMDRL	Biaxial motor driver long 29.5 mm	7290018434INS83
BXRDRS	Biaxial ratchet driver short 10 mm	7290018434INS83
BXRDRL	Biaxial ratchet driver long 15 mm	7290018434INS83

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Appendix 2: List of Applicable Standards

#	Standard number	Standard description	Reference No. of the harmonized standard - MDR 2017/745/ BS EN adopted
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.	ISO 13485:2016	Quality Systems-Medical Devices-System requirements for regulatory purposes	EN ISO 13485:2016/A11:2021
4.	TGA Regulation	Australian Regulatory Guidelines for Medical Devices (ARGMD)	
5.	ISO 10993-1:2018	Biological evaluation of medical devices. Part 1: Evaluation and testing	BS EN ISO 10993-1:2020
6.	ISO 14971:2019	Medical Devices-Application of risk management to medical devices within a risk management process	BS EN ISO 14971:2019/A11:2021
7.	ISO 15223-1:2021 Amd.1:2025	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	EN ISO 15223-1:2021
8.	ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer	BS EN ISO 20417:2021
9.	ISO 17665:2024	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	BS EN ISO 17665:2024
10.	ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices	BS EN ISO 17664-1:2021
11.	EN 62366-1:2015/Amd 1:2020	Medical devices - application of usability engineering to medical devices	-
12.	ASTM D4169-24	Standard Practice for Performance Testing of Shipping Containers and Systems	
13.	ASTM D5276-23	Standard Test Method for Drop Test of Loaded Containers by Free Fall	
14.	ASTM D642-20	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads	
15.	ASTM D4728: 17 (2022)	Standard Test Method for Random Vibration Testing of Shipping Containers	
16.	ASTM D999-08 (2015) 2023	Standard Test Methods for Vibration Testing of Shipping Containers	
17.	ASTM D4332-22	Standard Practice For Conditioning Containers, Packages, Or Packaging Components For Testing (Standard + Redline PDF Bundle)	