



EC DECLARATION OF CONFORMITY

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Medyssey.Co.,Ltd

129, Hanbang Expo-ro, Jecheon-si, Chungcheongbuk-do, 27116, Republic of Korea

Declares that the medical device(s) described hereafter

Reusable surgical instrument

Product name, Ref. No. : *Attached in Appendix A*

have been classified as Class I (Annex IX Rule 6). These products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC

and are in conformity with the national standards transposing harmonized standards EN ISO 14971:2012, EN ISO 13485:2012, EN ISO 10993-1:2009, EN ISO 14630:2012, EN 15223-1:2016, EN ISO 17665-1:2006, EN ISO 17664:2017

and are subject to the procedure set out in Annex VII of Directive 93/42/EEC as amended by Directive 2007/47/EC.

7 September 2018

Medyssey Co., Ltd.

J. W. Jang / President

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J.W. Jang

President

On behalf of Medyssey Co., Ltd.

EU Representative

Emergo

Prinsessegracht 20, 2514 AP The Hague, The Netherlands



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[Appendix A]

Reference Number and Product Description

1. Iliad Spinal System Instrument

Reference No.	Product Description	Reference No.	Product Name
NGTH-001	T-Holder	NNIR-002	INSERTER
NCSL-002	SCREW LEVER	NNPS-002	PERSUADER
NNCO-002	COMPRESSOR_PARALLEL - Ti	NNMD-111	MONO SCREW DRIVER_T-HANDLE
NNDR-002	DISTRACTOR_PARALLEL - Ti	NNPD-111	POLY SCREW DRIVER
NNRB-101	ROD BENDER_NEW	NNAT-202	ANTI-TORQUE WRENCH_STANDARD
NNTW-S03	TORQURE WRENCH_CLICKING	NCGT-002	GUIDE PIN_TIP
NNSD-S03	SET SCREW DRIVER	NCGN-002	GUIDE PIN_NONE TIP
NCTT-155	TAPS_Ø5.5	NCTS-101	TESTER_SINGLE
NCTT-165	TAPS_Ø6.5	NCTD-101	TESTER_DOUBLE
NCTT-175	TAPS_Ø7.5	NNRR-001	REDUCTION TAB REMOVER
NCAW-L15	AWL- 15mm	NNSS-001	SET SCREW STARTER - Single
NNCT-101	CROSS LINK DRIVER_T-HANDLE	NTRD-001	ROD DEROTATOR
NCPN-S11	PROBE_BLUNT NARROW_STRAIGHT	NNRH-002	ROD HOLDER
NCPN-C11	PROBE_BLUNT NARROW_CURVED	NN3-006	CASE_INSTRUMENT
NNRF-002	ROD FORK_LONG HANDLE	MN3-006	CASE_IMPLANT
NNRP-002	ROD PUSHER	MN3E-001	Cross Link Caddy

2. ArteMIS Spinal System Instrument

Reference No.	Product Description	Reference No.	Product Name
NXSD-001	Set Screw driver - Modular	NXRI-003	MIS Rod inserter 105°
NXAR-001	MIS Tap alignment tool	NXRR-001	MIS Reduction tap remover
NXAT-002	MIS Anti torque handle	NXSC-001	MIS Cap
NXCA-C15	MIS AWL_Cannulated_wire Holding 15mm	NXSR-001	MIS Ring
NXCP-003	MIS Compressor Parallel	NXTP-001	MIS T-Plate
NXCS-003	MIS Compression Sleeve - Modular	NXTS-S55	MIS Tap Sharp Type Ø 5.5
NXDA-010	MIS Dilator 10mm	NXTS-S60	MIS Tap Sharp Type Ø 6.0
NXDA-013	MIS Dilator 13mm	NXTS-S65	MIS Tap Sharp Type Ø 6.5
NXDA-S16	MIS Dilator PPU&Short 16.4mm	NXTS-S75	MIS Tap Sharp Type Ø7.5
NXKW-001	MIS Guide Wire	NXVC-001	MIS Scissors caliper
NXPD-001	MIS Cann. poly screw driver	NXWH-002	MIS K WIRE HOLDER



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Reference No.	Product Description	Reference No.	Product Name
NCTR-200	Trial rod 200mm	NXHA-001	MIS Head adjuster
NNRI-201	Straight Ratchet	MNX-001	MIS Zenius implant case
NNRT-201	T - Ratchet	MST-001	MIS Zenius set screw caddy
NNSO-001	Iliad Set Screw Starter double	NNX-001	MIS Zenius instrument case
NNTW-S13	Torque Wrench 13Nm	NNX-R01	Cap & Ring Caddy

3. LP Cage

Reference No.	Product Description	Reference No.	Product Name
NLCH-BT1	LP Cage Holder - T handle	NGSV-112	SHAVER - 12mm
NGH001	T-HOLDER	NGSV-113	SHAVER - 13mm
NGDT-108	DISTRACTOR - 8mm	NGSV-114	SHAVER - 14mm
NGDT-109	DISTRACTOR - 9mm	NDBP-001	BONE PACKING BAR
NGDT-110	DISTRACTOR - 10mm	NLFI-001	FINAL IMPACTOR
NGDT-111	DISTRACTOR - 11mm	NGOC-008	CURETTE - Large 8mm
NGDT-112	DISTRACTOR - 12mm	NGOC-006	CURETTE - Small 6mm
NGDT-113	DISTRACTOR - 13mm	NGRS-108	RASP - 8mm
NGDT-114	DISTRACTOR - 14mm	NGRS-110	RASP - 10mm
NGDT-115	DISTRACTOR - 15mm	NDPF-001	PLATFORM
NGSV-107	SHAVER - 7mm	NGNR-S01	NERVE RETRACTOR - Small
NGSV-108	SHAVER - 8mm	NGNR-L01	NERVE RETRACTOR - Large
NGSV-109	SHAVER - 9mm	NLPE-001	IMPLANT CASE
NGSV-110	SHAVER - 10mm	NLP-002	INSTRUMENTS CASE
NGSV-111	SHAVER - 11mm		

4. Athena Cervical Plate

Reference No.	Product Description	Reference No.	Product Name
APFP-001	Fixation Pin	APDG-006	Double Drill Guide (Middle-Hole)
APFH-002	Fixation Pin Holder	APSD-T10	Screw Driver (Locking)
APPH-001	Plate Holder	APRE-001	Ring Expander(Removal)
APBD-001	Plate Bender	APVC-002	Calipers
APAW-001	AWL (2.0mm - Trocar tip)	NCPH-001	Plastic Hammer
APTP-001	TAP (4.0)	NAP-002	Instrument Tray
APTP-002	TAP (4.5)	MCT-001	Implant Caddy (1,2Levels)
APQH-001	Quick Handle	MCT-002	Implant Caddy (3Levels)
APDB-002	Drill bit (Φ2.5)	MCT-003	Implant Caddy (4Levels)
APDG-001	SingleDrill Guide (Variable)	MCS-001	Implant Caddy (Variable Screw)
APDG-005	Double Drill Guide (End-Hole)		



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5. C7 Cage

Reference No.	Product Description	Reference No.	Product Name
N7CH-S01	C7 Holder set - Standard	N7TR-D267	Trial 6 & 7mm 12 x 14mm
N7BI-001	Bone Impactor	N7TR-D289	Trial 8 & 9mm 12 x 14mm
N7PB-001	Packing Block	N7TR-D445	Trial 4 & 5mm 14 x 16mm
N7PH-A01	Pin Holder	N7TR-D467	Trial 6 & 7mm 14 x 16mm
N7DP-A14	Distraction pin - L-14mm	N7TR-D489	Trial 8 & 9mm 14 x 16mm
N7DS-101	Distractor Mutual	NGBC-I01	Box Curettes
N7MA-001	Mallet	NC7E-006	C7 Cage and Trial Caddy
N7TR-D245	Trial 4 & 5mm 12 x 14mm	NC7-003	C7 Cage Instrument Tray

6. Unicorn-CS Cage

Reference No.	Product Description	Reference No.	Product Name
APQH-001	Quick Handle	UNSD-S01	Straight Screw driver
N7PH-A01	Pin Holder	UNPB-024	Packing block
N7DS-A01	Distractor	UNHM-001	Mallet
N7DP-A14	Distraction pin L-14mm	UNFO-001	Forcep
UNTR-C49	Trial 14x16x9mm	UNFI-001	Final impactor
UNTR-C48	Trial 14x16x8mm	UNDB-016	Drill bit 12mm
UNTR-C47	Trial 14x16x7mm	UNDB-014	Drill bit 14mm
UNTR-C46	Trial 14x16x6mm	UNDB-012	Drill bit 16mm
UNTR-C45	Trial 14x16x5mm	UNCH-001	Cage holder
UNTR-C29	Trial 12x14x9mm	UNBI-001	Bone impactor
UNTR-C28	Trial 12x14x8mm	UNAW-S01	Awl
UNTR-C27	Trial 12x14x7mm	UNAW-A01	Awl Angled
UNTR-C26	Trial 12x14x6mm	UNTW-H0.9	Torque Wrench 0.9N.m
UNTR-C25	Trial 12x14x5mm	UCST-001	Implant Caddy
UNSS-T07	Screw starter	UCS-001	Instrument tray
UNSD-U01	Universal joint Screw driver		

7. Poseidon

Reference No.	Product Description	Reference No.	Product Name
PNTW-H3.8	Torque Wrench 3.8N.m	PNPR-001	Probe
PNPD-H01	Poly screw Driver With Plastic Grip	PNDG-001	Drill Guide
PNSD-001	Screw Driver T15	PNDG-011	OCT Drill Guide 14&16mm
PNSD-002	Screw Driver (Long) T15	PNDG-021	OCT Drill Guide 10&12mm
PNAW-001	AWL	PNDG-031	OCT Drill Guide 6&8mm



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Reference No.	Product Description	Reference No.	Product Name
PNDB-025	Drill Bit ø2.5	PNBI-L01	Bending Irons Left
PNDB-030	Drill Bit ø3.0	PNBI-R01	Bending Irons Right
PNTP-035	Taps ø3.5	PNPS-001	Persuader
PNTP-040	Taps ø4.0	PNDP-001	Depth Gauge
PNAT-001	Anti-Torque	PNRD-001	Rod Derotator
PNAT-011	OCT Anit-Torque	PNRC-001	Rod Cutter
PNAL-001	Aligment Tool	PNCO-001	Compressor
PNCD-001	Crosslink Driver Hex 5.01	PNDR-001	Distractor
PNCD-002	Crosslink Driver Hex 8.01	PNRB-001	Rod Bender
PNHH-001	Hook Holder	PNST-001	Starter - Double
PNHF-001	Hook Finder	PNRP-001	Rod Pusher
PNJD-D30	Joint Drill Bit	PNCH-001	Cross Link holder
PNJD-T45	Joint Tap 4.5mm	APQH-001	Quick Handle
PNJD-S01	Joint Screw Driver	MPO-SC1	Screw Caddy
PNTS-002	Tester	MPO-RC1	Rod Caddy
PNTE-110	Template 110mm	MPO-CC1	Connector Caddy
PNTE-240	Template 240mm	MPO-001	Implant tray
PNRH-001	Rod Holder	NPO-001	Instrument Tray

8. Taurus-P Cage

Reference No.	Product Description	Reference No.	Product Name
NGSV-107	Shaver Due 7mm	NGTH-001	T-Holder
NGSV-108	Shaver Due 8mm	NTCH-AT1	Tautus Holder Set - TLIF T-HANDLE
NGSV-109	Shaver Due 9mm	N7BI-001	Bone Impactor
NGSV-110	Shaver Due 10mm	NTPB-001	Packing block
NGSV-111	Shaver Due 11mm	NGNR-L01	Nerve Retractor - Large
NGSV-112	Shaver Due 12mm	NGNR-S01	Nerve Retractor - Small
NGSV-113	Shaver Due 13mm	NGIP-C01	Straight impactor - 6mm
NGSV-114	Shaver Due 14mm	NGIP-S01	Curve impactor - 6mm
NTTR-D08	Trial 8mm	NGRS-801	45° Angled Rasp Angled - Dual Sided 5.5 x 8 mm
NTTR-D09	Trial 9mm	NGRC-007	Straight Ring Curette ø7.0 mm
NTTR-D10	Trial 10mm	NGBC-L01	45° Angled Box curette - Left 7x12 mm
NTTR-D11	Trial 11mm	NGBC-R01	45° Angled Box curette - Right 7x12 mm
NTTR-D12	Trial 12mm	NGAC-L01	Angled Cup curette - Left ø5.5
NTTR-D14	Trial 14mm	NGAC-R01	Angled Cup curette - Right ø5.5



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Reference No.	Product Description	Reference No.	Product Name
NGCC-S01	Straight Cup curette ϕ 5.5	NTBG-FL1	Bone Graft Funnel ϕ 6.0
NGCC-R01	Cup Curette Reverse Angle Straight ϕ 5.5	NTHM-001	Slap Hammer
NGOT-801	Straight Osteotome 8mm	NTIM-021	Cage caddy
NGLS-001	Lamina Spreader	NTC-002	TLIF cage instrument tray
NTBG-IL1	Bone Graft impactor ϕ 6.0		

9. Taurus-AL Cage

Reference No.	Product Description	Reference No.	Product Name
SATH-O210	Fix OLIF Trial -12° 10mm	NAFI-002	Final Impactor -OLIF
SATH-O212	Fix OLIF Trial -12° 12mm	NACH-001	Cage Holder -ALIF
SATH-O214	Fix OLIF Trial -12° 14mm	NACH-002	Cage Holder - OLIF
SATH-O216	Fix OLIF Trial -12° 16mm	NARS-001	RASP 6mm
SATH-O218	Fix OLIF Trial -12° 18mm	NAEE-001	Endplate Elevator
SATH-O810	Fix OLIF Trial -18° 10mm	NACC-A3.5	Cup Curette(Angle) - 3.5 x 4.5mm
SATH-O812	Fix OLIF Trial -18° 12mm	NACC-A7.5	Cup Curette(Angle) - 7.5 x 11.5mm
SATH-O814	Fix OLIF Trial -18° 14mm	NACC-5.5	Cup Curette - 5.5 x 8.5mm
SATH-O816	Fix OLIF Trial -18° 16mm	NACC-7.5	Cup Curette - 7.5 x 11.5mm
SATH-O818	Fix OLIF Trial -18° 18mm	NABC-006	Box Curette 6.0 x10mm
SATH-A212	Fix ALIF Trial -12° 12mm	NARC-A08	Ring Curette Angle 8mm
NAHM-002	Hammer	NARO-004	Rounger - 4mm
NGTH-101	T-Handle Long	NARO-006	Rounger - 6mm
NAPF-001	Platform	NAC-IC1	Implant Caddy 2 Gather cage
UNBI-001	Bone Impactor	NOC-IC1	Implant Caddy Keystone cage
NAFI-001	Final Impactor - ALIF	NOC-001	Instrument tray

10. Additional Instrument

Reference No.	Product Description	Reference No.	Product Name
ILIAD			
NCPK-S11	Lenke probe - Straight	NNRI-201	Ratchet - I
NCPK-C11	Lenke probe - Curve	NNRT-201	Ratchet - T
NCTM-R55	Modular Tap 5.5mm	NNPR-001	Push Tap Remover
NCTM-R65	Modular Tap 6.5mm	NNPD-R01	Modular Poly-axial Screw driver
NCTM-R75	Modular Tap 7.5mm	NNMD-R01	Modular Poly-axial Screw driver
NNFD-002	Head adjuster	NCRC-001	Rod Cutter



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Reference No.	Product Description	Reference No.	Product Name
Deformity			
NNCO-002L	Compressor - Large	NCDB-001	Derotation Bar
NNDR-002L	Distractor - Large	NCVG--001	Vise Grip
NNDC-001	Double Driver - Hex 3.5/4.0	NCAT-001	Alignment Tool - Large
NNDC-002	Double Driver - Hex 3.0/4.0	NCAT-002	Alignment Tool - Small
NTSB-L01	Single Bender - Left	NHLF-501	Larminar Hook Finder - 5mm
NTSB-R01	Single Bender - Right	NHLF-701	Larminar Hook Finder - 7mm
NCCB-L01	Coronal Bender - Left	NHPF-501	Pedicular Hook Finder - 5mm
NCCB-R01	Coronal Bender - Right	NHPF-701	Pedicular Hook Finder - 7mm
NNRC-001	Rod reducer	NHLH-001	Hook Impactor
NCRE-A01	Reduction Dirver Adapter	SNEM-102	Endmill -Modular
ArteMIS			
NXRT-150	Retractor Tube - 22mmx50mm	NXRA-R60	Retractor Blade,18x60mm - Right
NXRT-160	Retractor Tube - 22mmx60mm	NXRA-L70	Retractor Blade,18x70mm - Left
NXRT-170	Retractor Tube - 22mmx70mm	NXRA-R70	Retractor Blade,18x70mm - Right
NXRT-180	Retractor Tube - 22mmx80mm	NXRA-L80	Retractor Blade,18x80mm - Left
NXRT-050	Retractor Tube - 26mmx50mm	NXRA-R80	Retractor Blade,18x80mm - Right
NXRT-060	Retractor Tube - 26mmx60mm	NXRB-L40	Retractor Blade,22x40mm - Left
NXRT-070	Retractor Tube - 26mmx70mm	NXRB-R40	Retractor Blade,22x40mm - Right
NXRT-080	Retractor Tube - 26mmx80mm	NXRB-L50	Retractor Blade,22x50mm - Left
NXRT-D01	MIS Retractor - Loading Base	NXRB-R50	Retractor Blade,22x50mm - Right
NXFC-001	Ring Retractor Forceps	NXRB-L60	Retractor Blade,22x60mm - Left
NXRA-L40	Retractor Blade,18x40mm - Left	NXRB-R60	Retractor Blade,22x60mm - Right
NXRA-R40	Retractor Blade,18x40mm - Right	NXRB-L70	Retractor Blade,22x70mm - Left
NXRA-L50	Retractor Blade,18x50mm - Left	NXRB-R70	Retractor Blade,22x70mm - Right
NXRA-R50	Retractor Blade,18x50mm - Right	NXRB-L80	Retractor Blade,22x80mm - Left
NXRA-L60	Retractor Blade,18x60mm - Left	NXRB-R80	Retractor Blade,22x80mm - Right
Cervical Retractor Set			
N7AC-A01	Articulating Arm	N7RB-050	Retractor Blade 50mm
N7AC-B01	Table clamp	N7RB-055	Retractor Blade 55mm
N7AC-C01	Rack Connector	N7RB-060	Retractor Blade 60mm
N7RB-040	Retractor Blade 40mm	N7RT-L01	Retractor Double Hinge
N7RB-045	Retractor Blade 45mm	N7RB-001	Handle for Retractor Blade