

EU DECLARATION OF CONFORMITY

Manufacturer's name	mdh sp. z o. o.	
Manufacturer's address	ul. Maratońska 104, 94-007 Łódź, Poland	
SRN (Single Registration Number)	PL-MF-000011406	
Classification	Class I	
Rule of classification	Rule 1, Annex VIII, Regulation (EU) 2017/745	
Conformity assessment route	Annex II+III, Regulation (EU) 2017/745	

This declaration of conformity is issued under the sole responsibility of mdh sp. z. o. o. We hereby declare that the medical devices specified below (Annex I), marked CE, meet the provision of the Regulation (EU) MDR 2017/745 for medical devices and complies with standards.

PN-EN ISO 13485:2016-04

PN-EN ISO 14971:2020-05

PN-EN ISO 15223-1:2022-01

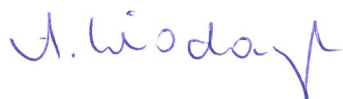
PN-EN ISO 20417:2021-10

PN-EN ISO 22523:2007

(applied standards)

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(company stamp)

Issue date: 18.10.2022

Place of issue: Łódź, Poland

Annex I

Trade name of device	Brand name	Catalogue number	Sizes	Basic UDI-DI
4-Arm non-woven fabric sling	Qmed	DRQG0A	S-L	59017804DRQG0ALL
Abdominal binder	Qmed	DRQH6	S-XXL	59017804DRQH6PN9
Abdominal binder universal	Qmed	BPASO	XS-XXXL	59017804BPASPJ
Achillo Medical Achilles tendon bandage with gel pads	Meyra Medical	MY2721	1-5	59017804MY2721GZ
Acromed	Qmed	DRQJ0B	1-5	59017804DRQJ0BM5
AeroStab	Qmed	DRQI0P	S-L	59017804DRQI0PMU
AeroStab PRO SPORT Stabilizing Ankle Brace	Qmed by Meyra	DRQI0W	S-L	59017804DRQI0WNA
AFO-Fit	Qmed	DRQI1A	S-XL	59017804DRQI1ALZ
AFO-Night	Qmed	DRQI3A	S-L	59017804DRQI3AM7
AFO-Soft	Qmed	DRQI0H	S-L	59017804DRQI0HMC
AFO-Walker ¾	Qmed	DRQI3H	S-L	59017804DRQI3HMM
Air Walking Boot	Qmed	DRQI5E, DRQI5F	S-XL	59017804DRQI5EMM
Ankle Stabilizing Orthosis	Qmed 3D Line	DRQI5C	S-XL	59017804DRQI5CMH
Arm Abduction Orthosis	Qmed Silver Line	QSM00020 QSM00030 QSM00040 QSM00050	S-XL	59017804QSM000LW
Arm abduction orthosis	Qmed	DRQJ0A	S-L	59017804DRQJ0AM3
Arm Sling	Qmed Pharma	PHAG01	S-XXL	59017804PHAG01HL
As-15 Medical arm sling with abduction cushion	Meyra Medical	MY2721	1-3	59017804MY2721GZ
As-Basic Medical arm sling	Meyra Medical	MY275201	1-3	59017804MY275201HJ
Clavicle Support	Qmed Silver Line	QSM00091	Universal	59017804QSM00091QB
Collar Stark	Meyra Medical	MQA2D	S-XL	59017804MQA2DLQ
Corset Premium	Qmed	DRQH0U	S-XXL	59017804DRQH0UMZ
DUO Hand orthosis stabilizing fingers	Qmed by Meyra	DRQF3H	Universal	59017804DRQF3HM6
Elbow joint orthosis	Qmed Silver Line	QEM061/62	Universal	59017804QEM06LC
Elbow Orthosis	Qmed 3D Line	DRQF5C	S-XL	59017804DRQF5CM2
Elbow Rush	Qmed	DRQF0H	Universal	59017804DRQF0HLV
Elbow Safe	Meyra Medical	DRQF0G	1-5	59017804DRQF0GLT
Epi Medical elbow bandage	Meyra Medical	MY275101	0-6	59017804MY275101HD
First	Qmed	DRQI5A	XS-L	59017804DRQI5AMD
Follow	Qmed	DRQI0E	XS-XL	59017804DRQI0EM6
Follow Force Knee brace with regulated range of motion	Qmed	DRQI0Q	XS-XL	59017804DRQI0QMW
Foot and Shin Brace	Qmed Silver Line	QAM04010 QAM04020 QAM04030 QAM04040 QAM04050	XS-XL	59017804QAM040F4
Foot and Shin Brace	Qmed Silver Line	QAM04011	XS-XL	59017804QAM040F4

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(Pneumatic)		QAM04021 QAM04031 QAM04041 QAM04051		
FOOT-RISE Drop foot orthosis	Meyra Medical	MQB1F	S-L	59017804MQB1FLW
Genu Meyra bandage with silicone ring	Meyra Medical	MY271201	0-7; 3XL-7XL	59017804MY271201GN
Genu Meyra IMS knee immobilization splin	Meyra Medical	MY273	0-2	59017804MY273KR
Hip Orthosis	Qmed	DRQ10B	S-XL	59017804DRQ10BLY
Hyperextension Jewett Type	Qmed	DRQB	S-L	59017804DRQB0BKV
KAFO type brace	Qmed	DRQ15D	S - L	59017804DRQ15DMK
KID AEROSTAB Stabilizing Ankle Brace	Qmed	DRQ10T	XS, XXS, XXXS	59017804DRQ10TN4
KID AFO-SOFT Ankle Brace	Qmed	DRQ10U	Universal	59017804DRQ10UN6
KID AIR WALKING BOOT Foot and Shin brace	Qmed	DRQ15G	Universal	59017804DRQ15GMR
KID MANU UNIWERSAL LONG Wrist orthosis with a thumb hold	Qmed	DRQF3G	Universal	59017804DRQF3GM4
KID MANU UNIWERSAL Wrist orthosis with a thumb hold	Qmed	DRQF3F	Universal	59017804DRQF3FM2
KID PROSPINE Clavicle Support	Qmed	DRQH0W	Universal	59017804DRQH0WN5
KID RUSH Post-operative knee brace	Qmed	DRQ10V	Universal	59017804DRQ10VN8
Knee Orthosis	Qmed 3D Line	DRQ15B	S-XL	59017804DRQ15BMF
Kneemotion II	Qmed Active Line	DRQ10G	1-6	59017804DRQ10GMA
Knitted Ankle Stabilizer	Qmed Pharma	PHAI01	S-XL	59017804PHAI01HW
Knitted Elbow Stabilizer	Qmed Pharma	PHAF01	S-XL	59017804PHAF01HF
Knitted Knee Stabilizer	Qmed Pharma	PHAI02	S-XL	59017804PHAI01HW
Knitted Wrist Stabilizer	Qmed Pharma	PHAF02	S-XL	59017804PHAI01HW
LS Support	Qmed Silver Line	QBE01020 QBE01030 QBE01040 QBE01050 QBE01060	S-XXL	59017804QBE010DE
Lumbar Support	Qmed	DRQE0D	Universal	59017804DRQE3DLR
Lumbo Medical Comfort lumbar bandage with sacrum pad	Meyra Medical	MY271101, MY271301	1-6	59017804MY271101GH
Lumbo Medical Light lumbar support bandage with stabilization struts	Meyra Medical	MY274101	1-6	59017804MY274101H6

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Lumbo Medical lumbar bandage with sacrum pad	Meyra Medical	MY274201	1-6	59017804MY274201HB
Lumbo Medical Pro lumbar bandage with stabilization struts	Meyra Medical	MY274401	1-6	59017804MY274401HM
Lumbosacral Corset	Qmed Pharma	PHAH01	S-XL	59017804PHAH01HR
Malleo Medical ankle joint bandage with gel pads	Meyra Medical	MY274301	1-6	59017804MY274301HG
Manu Universal	Qmed	DRQF3C	Universal	59017804DRQF3CLU
Manu Universal Long	Qmed	DRQF3E	Universal	59017804DRQF3ELY
Manu Medical Plus wrist orthosis with thumb hold	Meyra Medical	MY2761	1-4	59017804MY2761HD
Manu Medical wrist orthosis	Meyra Medical	MY2762	1-4	59017804MY2762HF
Manu Meyra Comfort wrist orthosis	Meyra Medical	MY2765	1-6	59017804MY2765HM
Motive	Qmed	DRQI0C	1-5	59017804DRQI0CM2
Motive Plus	Qmed	DRQI0S	1-5	59017804DRQI0SN2
NT-Bac Collar	Qmed	DRQA0B	Height 29.5-44.6 cm, Circumference 7-12 cm	59017804DRQA0BKQ
NT-Bac Plus Collar	Qmed	DRQA0C	Height 29.5-44.6 cm, Circumference 7-12 cm	59017804DRQA0CKS
ONE Hyperextension brace Jewett type.	Qmed	DRQB0E	S-XL	59017804DRQB0EL3
One Occiput and mandible support	Qmed	DRQP0G	Universal	59017804DRQP0GND
Orthopaedic Collar	Qmed	DRQA0A	S-L	59017804DRQA0AKN
Orthopaedic Vest	Qmed	DRQC	R0 – R5	59017804DRQCQS
Padded lumbosacral support	Qmed	BPASKO	XS-XXXL	59017804BPASKOLS
Patella Tendon Strap	Qmed Silver Line	QKN00091	Universal	59017804QKN00091LG
Post OP Knee Brace	Qmed by Meyra	QKM0609	Universal	59017804QKM0609KJ
Post-operative knee brace with hinge	Qmed Silver Line	QKM06090	Universal	59017804QKM0609KJ
Postpartum binder	Qmed	BPASP	XS-XXXL	59017804BPASPLG
Power Walking Boot	Qmed Silver Line	Q62011	S-XL	59017804Q620115R
Premium S	Qmed	DRQH0R	S-XXL	59017804DRQH0RMT
Premium TLS	Qmed	DRQH0S	S-XXL	59017804DRQH0SMV
Prohand Wrist support	Meyra Medical	DRQF0F	Universal	59017804DRQF0FLR
Reflex Closed	Meyra Medical	MQB3M	XS-XXXL	59017804MQB3MMJ
Reflex Long Closed	Meyra Medical	MQB3O	XS-XXXL	59017804MQB3OMN
Reflex Long Wrap-Around	Meyra Medical	MQB3N	XS-XXXL	59017804MQB3NML
Reflex Wrap-Around	Meyra Medical	MQB3K	XS-XXXL	59017804MQB3KME
Rhizo Medical thumb orthosis	Meyra Medical	MY2765	1-3	59017804MY2765HM

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ROM Knee Brace Covering Shin and Thigh	Qmed	DRQI3S	Universal	59017804DRQI3SNB
RUSH	Qmed	DRQI0N	Universal	59017804DRQI0NMQ
S- Move (closed)	Qmed	DRQI0D	1-5	59017804DRQI0DM4
Scamper	Qmed	DRQI3T	S-XL	59017804DRQI3TND
Shin and Thigh Brace	Qmed Silver Line	QKM010	S-XXL	59017804QKM010J9
Sling with stabilization strap	Qmed Silver Line	QSM00090	Universal	59017804QSM000LW
S-Move (open)	Qmed	DRQI0I	1-5	59017804DRQI0IME
Spinactive	Qmed	DRQH0A	1-6	59017804DRQH0ALR
Spinactive-LSII	Qmed	DRQH0K	1-6	59017804DRQH0KMD
Spincare Cross	Qmed	DRQH0M	S-XXL	59017804DRQH0MMH
Spincare Extensor	Qmed	DRQH0L	1-6	59017804DRQH0LMF
Spincare Flex Spincare Flex II Spincare Flex III	Qmed	DRQH0B, DRQH0B1, DRQH0B1F	1-6	59017804DRQH0BLT
Spincare Frame	Qmed	DRQH0I	1-5	59017804DRQH0IM9
Spincare High	Qmed	DRQH0N	S-XXL	59017804DRQH0NMK
Spincare High Plus	Qmed	DRQH0P	S-XXL	59017804DRQH0PMP
Spincare PIN	Qmed	QBE23020	S-XXXL	59017804QBE23020CN
Spincare Rigid	Qmed	DRQH0C	1-6	59017804DRQH0CLV
Spincare Rigid II	Qmed	DRQH0J	1-5	59017804DRQH0JMB
Stabilizing Ankle Brace (Pneumatic Gel)	Qmed Silver Line	QAR03091	Universal	59017804QAR03091HF
Stabilizing Knee Brace	Qmed Silver Line	QKN01021 QKN01031 QKN01041 QKN01051	S-XL	59017804QKN010JG
Stabilizing Knee Brace	Qmed Silver Line	QKN04020 QKN04030 QKN04040 QKN04050	S-XL	59017804QKN010JG
Stack Apparatus	Qmed by Meyra	DRQF3A	2-7	59017804DRQF3ALQ
Stomia waistband	Qmed	BPASST	XS-XXXL	59017804BPASST24Z3
Support Stoma Waistband	Qmed	DRQH0T	XS-XXXL	59017804DRQH0TMX
Talu Medical stabilising ankle joint orthosis	Meyra Medical	MY2763	Universal	59017804MY2762HF
Torako binder	Qmed	BPASTOR	XS-XXXL	59017804BPASTORRR
Uni Hand	Qmed	DRQF3D	S-L	59017804DRQF3DLW
UNO Hand orthosis stabilizing fingers	Qmed by Meyra	DRQF3I	1, 2, additional stabilizer	59017804DRQF3IM8
WHOSP-F	Qmed	DRQF0C	S-L	59017804DRQF0CLK
WHOSP-FT	Qmed	DRQF0D	S-L	59017804DRQF0DLM
WHO-Stab Plus	Qmed	DRQF0B	S-L	59017804DRQF0BLH
Wrist and thumb support	Qmed Silver Line	Q42006	XS-L	59017804Q420006YF
Wrist Stabilizer	Qmed 3D Line	DRQF5A	S-XL	59017804DRQF5ALW

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Wrist Stabilizing Brace	Qmed 3D Line	DRQF5B	S-XL	59017804DRQF5BLY