

EU DECLARATION OF CONFORMITY

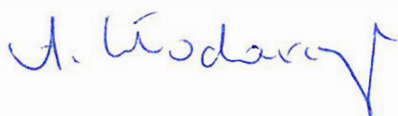
Manufacturer's name	mdh sp. z o. o.	
Manufacturer's address	ul. Maratońska 104, 94-007 Łódź, Poland	
SRN (Single Registration Number)	PL-MF-000011406	
Classification	Class I	
Rule of classification	Rule 1, Annex VIII, Regulation (EU) 2017/745	
Conformity assessment route	Annex II+III, Regulation (EU)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

MEMBER OF THE BOARD

Anetta Włodarczyk



MEMBER OF THE BOARD

Mariusz Gierałt



(name/function/signature)

mdh sp. z o.o.

94-007 Łódź, ul. Maratońska 104
tel. 42 674 83 84 : www.mdh.pl
NIP 7282295492 : REGON 472253652

(company stamp)

Issue date: 01.08.2022

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	DRQJOB	1-5	59017804DRQJOBM5
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
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 (Pneumatic)	Qmed Silver Line	QAM04011 QAM04021 QAM04031	XS-XL	59017804QAM040F4

Annex I

Trade name of device	Brand name	Catalogue number	Sizes	Basic UDI-DI
		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	DRQI0B	S-XL	59017804DRQI0BLY
Hyperextension Jewett Type	Qmed	DRQB	S-L	59017804DRQB0BKV
KAFO type brace	Qmed	DRQI5D	S - L	59017804DRQI5DMK
KID AEROSTAB Stabilizing Ankle Brace	Qmed	DRQI0T	XS, XXS, XXXS	59017804DRQI0TN4
KID AFO-SOFT Ankle Brace	Qmed	DRQI0U	Universal	59017804DRQI0UN6
KID AIR WALKING BOOT Foot and Shin brace	Qmed	DRQI5G	Universal	59017804DRQI5GMR
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	DRQI0V	Universal	59017804DRQI0VN8
Knee Orthosis	Qmed 3D Line	DRQI5B	S-XL	59017804DRQI5BMF
Kneemotion II	Qmed Active Line	DRQI0G	1-6	59017804DRQI0GMA
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

Annex I

Trade name of device	Brand name	Catalogue number	Sizes	Basic UDI-DI
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 Silver Line	QKM06091	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

Annex I

Trade name of device	Brand name	Catalogue number	Sizes	Basic UDI-DI
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	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
WHOSP-F	Qmed	DRQFOC	S-L	59017804DRQFOCLK
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
Wrist Stabilizing Brace	Qmed 3D Line	DRQF5B	S-XL	59017804DRQF5BLY