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QMED BY MEYRA

ES atbilstības deklarācija

EU Declaration of Conformity

Ražotāja nosaukums *Manufacturer's name*	**mdh sp. z o.o.**
Ražotāja adrese *Manufacturer's address*	**ul. Maratońska 104, 94-007 Łódź, Polija (ES)**
SRN (vienotais reģistrācijas numurs / Single Registration Number)	**PL-MF-000011406**
Klasifikācija *Classification*	**I klases risks / Class I risk**
Zīmols *Brand*	**QMED BY MEYRA**
Klasifikācijas noteikums *Rule of classification*	**1. noteikums, VIII pielikums, Regula (ES) 2017/745**
Atbilstības novērtēšanas procedūra *Conformity assessment route*	**II + III pielikums, Regula (ES) 2017/745**

Šī atbilstības deklarācija ir izsniegta vienīgi mdh sp. z o.o. atbildībā. Ar šo mēs apliecinām, ka turpmāk norādītās medicīniskās ierīces (I pielikums), kas marķētas ar CE zīmi, atbilst Regulas (ES) 2017/745 par medicīniskām ierīcēm (MDR) prasībām un atbilst šādiem standartiem.

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 provisions of Regulation (EU) MDR 2017/745 for medical devices and comply with the following 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

(piemērotie standarti / applied standards)

I PIELIKUMS / Annex I

Ierīces tirdzniecības nosaukums Trade name of device	Kataloga Nr. Catalogue number	Izmēri Sizes	EMDN kods EMDN codes	Basic UDI-DI
4-Arm (Non-woven fabric sling)	DRQG0A	S-L	Y060624	59017804DRQG0ALL
Abdominal binder	DRQH6	S-XXL	Y060499	59017804DRQH6PN9
Abdominal binder universal	BPASO	XS-XXXL	Y060499	59017804BPASPJ
Achillo Medical Achilles tendon bandage with gel pads	MY2721	1-5	Y06120601	59017804MY2721GZ
ACL RECOVER Functional knee brace	DRQI7D	L-XL	Y061209	59017804DRQI7DMR
Acromed	DRQJ0B	1-5	Y060621	59017804DRQJ0BM5
ActiveShoulder Shoulder and arm brace	DRQJ0C	universāls	Y060621	59017804DRQJ0CM7
AeroFit Ankle stabilisation brace	DRQI7G	S, M, L	Y06120601	59017804DRQI7GMX
AeroStab	DRQI0P	S-L	Y06120601	59017804DRQI0PMU
AeroStab PRO SPORT Stabilizing Ankle Brace	DRQI0W	S-L	Y06120601	59017804DRQI0WNA
AFO-Fit	DRQI1A	S-XL	Y06120601	59017804DRQI1ALZ
AFO-Night	DRQI3A	S-L	Y06120601	59017804DRQI3AM7
AFO-Soft	DRQI0H	S-L	Y06120601	59017804DRQI0HMC
AFO-Walker ¾	DRQI3H	S-L	Y06120601	59017804DRQI3HMM
Air Walking Boot	DRQI5E DRQI5F	S-XL	Y06120601	59017804DRQI5EMM
Ankle Stabilizing Orthosis	DRQI5C	S-XL	Y06120601	59017804DRQI5CMH
Arm Abduction Orthosis	QSM000	S-XL	Y060399	59017804QSM000LW
Arm abduction Orthosis	DRQJ0A	S-L	Y060624	59017804DRQJ0AM3
Arm Sling	PHAG01	S-XXL	Y060624	59017804PHAG01HL
ARMShell Shoulder and arm brace	DRQJ0D	universāls	Y060621	59017804DRQJ0DM9
As-15 Medical arm sling with abduction cushion	MY275201	1-3	Y060621	59017804MY2721GZ
As-Basic Medical arm sling	MY275101	1-3	Y060621	59017804MY275201HJ
CerviComfort FLORIDA Semi-rigid collar	DRQA0D	XS-XL	Y060312	59017804DRQA0DKU
Clavicle Support	QSM00091	universāls	Y060399	59017804QSM00091QB
Collar Stark	MQA2D	S-XL	Y060312	59017804MQA2DLQ
Corset Premium	DRQH0U	S-XXL	Y060308	59017804DRQH0UMZ

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DUO Hand orthosis stabilizing fingers	DRQF3H	universāls	Y060606	59017804DRQF3HM6
Elbow joint orthosis	QEM061/62	universāls	Y060615	59017804QEM06LC
Elbow Orthosis	DRQF5C	S-XL	Y060615	59017804DRQF5CM2
Elbow Rush	DRQF0H	universāls	Y060615	59017804DRQF0HLV
Elbow Safe	DRQF0G	1-5	Y060615	59017804DRQF0GLT
Epi Medical elbow bandage	MY273	0-6	Y060615	59017804MY275101HD
FINDER M2 Hinged knee brace	DRQI7J	S-XXL	Y06120601	59017804DRQI7JN5
Foot and Shin Brace	QAM040	XS-XL	Y06120601	59017804QAM040F4
First	DRQI5A	XS-L	Y061209	59017804DRQI5AMD
Follow	DRQI0E	XS-XL	Y061209	59017804DRQI0EM6
Follow Force Knee brace with regulated range of motion	DRQI0Q	XS-XL	Y061209	59017804DRQI0QMW
FOOT-RISE Drop foot orthosis	MQB1F	S-L	Y06120601	59017804MQB1FLW
Genu Meyra bandage with silicone ring	MY271101 MY271301	0-7; 3XL-7XL	Y061209	59017804MY271201GN
Genu Meyra IMS knee immobilization splin	MY271201	0-2	Y061209	59017804MY273KR
HIKE M4 Hinged knee brace	DRQI7K	S-XXL	Y061209	59017804DRQI7KN7
HIP BRACE Hip brace with flexion, extension and adduction adjustment range	DRQI7B	universāls	Y061215	59017804DRQI7BMM
Hip Orthosis	DRQI0B	S-XL	Y061215	59017804DRQI0BLY
HIP RUSH BASIC Hip brace with flexion angle adjustment	DRQI7M	universāls	Y061215	59017804DRQI7MNB
HIP RUSH Hip brace with flexion angle adjustment	DRQI0Z	universāls	Y061215	59017804DRQI0ZNG
Hyperextension brace type Jewetta; HX-3	Elastīga iegurņa josta (DRQB0B); Ar V veida stabilizatoru (DRQB0C); Universāla (DRQB0D)	S1, S2, S3, S4; M1, M2, M3, M4; L1, L2, L3, L4; S, M, L	Y060315	59017804DRQB0BKV
JointCraft 3D Knee brace with regulated range of motion	DRQI0X	universāls	Y061209	59017804DRQI0XNC
KAFO COMPACT Brace	DRQI7A	universāls	Y06121201	59017804DRQI7AMK
KAFO type brace	DRQI5D	S - L	Y06121201	59017804DRQI5DMK
KID AEROSTAB Stabilizing Ankle Brace	DRQI0T	XS, XXS, XXXS	Y06120601	59017804DRQI0TN4
KID AFO-SOFT Ankle Brace	DRQI0U	universāls	Y06120601	59017804DRQI0UN6
KID AIR WALKING BOOT Foot and Shin brace	DRQI5G	universāls	Y06120601	59017804DRQI5GMR
KID MANU UNIWERSAL LONG Wrist orthosis with a thumb hold	DRQF3G	universāls	Y060612	59017804DRQF3GM4
KID MANU UNIWERSAL Wrist orthosis with a thumb hold	DRQF3F	universāls	Y060612	59017804DRQF3FM2
KID PROSPINE Clavicle Support	DRQH0W	universāls	Y060399	59017804DRQH0WN5
KID RUSH Post-operative knee brace	DRQI0V	DRQI0V	Y061209	59017804DRQI0VN8
Knee Orthosis	DRQI5B	S-XL	Y061209	59017804DRQI5BMF
KneeGlide OA Knee brace	DRQI7F	universāls	Y061209	59017804DRQI7FMV
Kneemotion II	DRQI0G	1-6	Y061209	59017804DRQI0GMA
Knitted Ankle Stabilizer	PHAI01	S-XL	Y06120601	59017804PHAI01HW
Knitted Elbow Stabilizer	PHAF01	S-XL	Y060615	59017804PHAF01HF
Knitted Knee Stabilizer	PHAI02	S-XL	Y061209	59017804PHAI02HY
Knitted Wrist Stabilizer	PHAF02	S-XL	Y060612	59017804PHAF02HH
Lumbar and thoracic support	QBE010	S-XXL	Y060308	59017804QBE010DE
Lumbo Medical Comfort lumbar bandage with sacrum pad	MY274201	1-6	Y060308	59017804MY274201HB
Lumbo Medical Light lumbar support bandage with stabilization struts	MY274401	1-6	Y060308	59017804MY274401HM
Lumbo Medical lumbar bandage with sacrum pad	MY274101	1-6	Y060308	59017804MY274101H6
Lumbo Medical Pro lumbar bandage with stabilization struts	MY274301	1-6	Y060308	59017804MY274301HG
Lumbosacral Corset	PHAH01	S-XL	Y060308	59017804PHAH01HR
Malleo Medical ankle joint bandage with gel pads	MY2722	1-6	Y06120601	59017804MY2722H3
Manu Universal	DRQF3C	universāls	Y060612	59017804DRQF3CLU
Manu Universal Long	DRQF3E	universāls	Y060612	59017804DRQF3ELY

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Manu Medical Plus wrist orthosis with thumb hold	MY2761	1-4	Y060606	59017804MY2761HD
Manu Medical wrist orthosis	MY2762	1-4	Y060606	59017804MY2762HF
Manu Meyra Comfort wrist orthosis	MY2765	1-6	Y060606	59017804MY2765HM
MOTION M3 Hinged knee brace	DRQI7L	S-XXL	Y061209	59017804DRQI7LN9
Motive	DRQI0C	1-5	Y061209	59017804DRQI0CM2
Motive Plus	DRQI0S	1-5	Y061209	59017804DRQI0SN2
NEO WALKER Foot and shin brace	DRQI0Y	S, M, L	Y06120601	59017804DRQI0YNE
NT-Bac Collar	DRQA0B	augstums 29.5-44.6 cm, apkārtmērs 7-12 cm	Y060312	59017804DRQA0LG
NT-Bac Plus Collar	DRQA0C	augstums 29.5-44.6 cm, apkārtmērs 7-12 cm	Y060312	59017804DRQA0LG
Oasis OA Knee brace	MQB3I	universāls	Y061209	59017804MQB3IMA
ONE Hyperextension brace Jewett type.	DRQB0E	S-XL	Y060315	59017804DRQB0EL3
One Occiput and mandible support	DRQP0G	universāls	Y060315	59017804DRQP0GND
Orthopaedic Collar	DRQA0A	S-L	Y060312	59017804DRQA0AKN
Orthopaedic Vest	DRQC	R000, R00, R0, R1, R2, R3, R4, R5	Y060624	59017804DRQCQS
Padded lumbosacral support	BPASKO	XS-XXXL	Y060399	59017804BPASKOLS
Patella Tendon Strap	QKN00091	universāls	Y061209	59017804QKN00091LG
Post OP Knee Brace (with or w/o hinge)	QKM0609	universāls	Y061209	59017804QKM0609KJ
Postpartum binder	BPASP	XS-XXXL	Y060499	59017804BPASPLG
Power Walking Boot	Q62011	S-XL	Y06120601	59017804Q620115R
Premium S	DRQH0R	S-XXL	Y060308	59017804DRQH0RMT
Premium TLS	DRQH0S	S-XXL	Y060308	59017804DRQH0SMV
Prohand Wrist support	DRQF0F	universāls	Y060612	59017804DRQF0FLR
Reflex Closed	MQB3M	XS-XXXL	Y061209	59017804MQB3MMJ
Reflex Long Closed	MQB3O	XS-XXXL	Y061209	59017804MQB3OMN
Reflex Long Wrap-Around	MQB3N	XS-XXXL	Y061209	59017804MQB3NML
Reflex Wrap-Around	MQB3K	XS-XXXL	Y061209	59017804MQB3KME
Rhizo Medical thumb orthosis	MY2763	1-3	Y060603	59017804MY2763HH
ROM Knee Brace Covering Shin and Thing	DRQI3S	universāls	Y061209	59017804DRQI3SNB
Rush Post-operative knee brace (brace on the shin and thigh)	DRQI0N	universāls	Y061209	59017804DRQI0NMQ
S-MOVE Knee brace with flexion angle adjustment	Slēgta (DRQI0D) Atvērta (DRQI0I)	1-5	Y061209	59017804DRQI0DM4
Scamper Pneumatic boot with pressure control	DRQI3T	S-XL	Y06120601	59017804DRQI3TND
SECOND Functional knee brace	DRQI7H	XS-L	Y061209	59017804DRQI7HMZ
Shin and Thigh Brace	QKM010	S-XXL	Y061209	59017804QKM010J9
SHOULDER IMMOBILIZER 15 Shoulder joint abduction brace	DRQJ0F	universāls	Y060621	59017804DRQJ0FMD
SHOULDER IMMOBILIZER 45 Shoulder joint abduction brace	DRQJ0E	S-XL	Y060621	59017804DRQJ0EMB
Sling with stabilization strap	QSM00090	universāls	Y060624	59017804QSM000LW
SPINACTIVE	DRQH0A	1-6	Y060308	59017804DRQH0ALR
SPINACTIVE -LSII	DRQH0K	1-6	Y060308	59017804DRQH0KMD
Spincare Cross	DRQH0M	S-XXL	Y060308	59017804DRQH0MMH
Spincare Extensor	DRQH0L	1-6	Y060399	59017804DRQH0LMF
Spincare Flex Spincare Flex II Spincare Flex III	DRQH0B, DRQH0B1, DRQH0B1F	1-6	Y060308	59017804DRQH0BLT
Spincare Frame	DRQH0I	1-5	Y060308	59017804DRQH0IM9
Spincare High	DRQH0N	S-XXL	Y060308	59017804DRQH0NMK
Spincare High Plus	DRQH0P	XS- XXXXL	Y060308	59017804DRQH0PMP
Spincare PIN	QBE23020	S-XXXL	Y060308	59017804QBE23020CN
Spincare Rigid	DRQH0C	1-6	Y060308	59017804DRQH0CLV
Spincare Rigid II	DRQH0J	1-5	Y060308	59017804DRQH0JMB
Stabilizing Ankle Brace (Pneumatic Gel)	QAR03091	universāls	Y06120601	59017804QAR03091HF

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Stabilizing Knee Brace	Ar saliekšanas leņķa regulēšanu (QKN040); Bez saliekšanas leņķa regulēšanas (QKN010)	S-XL	Y061209	59017804QKN010JG
StabROM OA Knee brace	DRQI7E	S-XL	Y061209	59017804DRQI7EMT
Stack Apparatus	DRQF3A	2-7	Y060603	59017804DRQF3ALQ
Stomia waistband	BPASST	XS-XXXL	Y060499	59017804BPASST24Z3
STRIDE SUPPORT Functional knee brace with frame construction	DRQI7C	S-XL	Y061209	59017804DRQI7CMP
SUPER CARE Functional knee brace with frame construction	DRQI7I	S-XL	Y061209	59017804DRQI7IN3
Support Stoma Waistband	DRQH0T	XS-XXXL	Y060499	59017804DRQH0TMX
Talu Medical stabilising ankle joint orthosis	MY272131	universāls	Y06120601	59017804MY2762HF
Torako binder	Sieviešu (BPSTORD), Vīriešu (BPSTORM)	XS-XXXL	Y060307	59017804BPASTORRR
Uni Hand	DRQF3D	S-L	Y060619	59017804DRQF3DLW
UNO Hand orthosis stabilizing fingers	DRQF3I	1, 2, papildu stabilizators	Y060606	59017804DRQF3IM8
WHOSP Hand and forearm splint	FT (DRQF0D); F (DRQF0C)	S-L	Y060612	59017804DRQF0LX
WHO-Stab Plus	DRQF0B	S-L	Y060606	59017804DRQF0BLH
Wrist and thumb support	Q42006	XS-L	Y060612	59017804Q420006YF
Wrist Stabilizer	DRQF5A	S-XL	Y060612	59017804DRQF5ALW
Wrist Stabilizing Brace	DRQF5B	S-XL	Y060612	59017804DRQF5BLY

Uzņēmumu pārstāvošās personas / Company represented by

Valdes locekle / Member of the Board
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Izdevums, 2025-07-16 – derīgs līdz nākamā izdevuma datumam.
Tulkojums no angļu valodas oriģināla (EU Declaration of Conformity, QMED BY MEYRA, izdota 16.07.2025). Tirdzniecības nosaukumi, kodi un identifikatori atstāti kā oriģinālā.