

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 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

(applied standards)

MEMBER OF THE BOARD

Anetta Włodarczyk



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(company stamp)

Issue date: 01.08.2022

Place of issue: Łódź, Poland

Annex I

Trade name of device	Brand name	Catalogue number	Basic UDI-DI
¼ Healthy Insoles	Qmed	I102	59017804DRIDORKF
ABS Gym Ball	Qmed	DRQM	59017804DRQM3AMT
ABS Gym Ball – Peanut	Qmed Active	DRQM3I	59017804DRQM3I0Q7
Anti Snoring Pillow	Qmed	DRQR3C	59017804DRQR3CNQ
Arch Pillow	Qmed	DRQE3G	59017804DRQE3GLX
Baby Pillow	Qmed	DRQE3C	59017804DRQE3CLP
Back Stretching Support	Qmed	DRQE3J	59017804DRQE3JM5
Balance Disc	Qmed	DRQM3C	59017804DRQM3CMX
Balance Pad	Qmed	DRQM3F	59017804DRQM3FN5
Balance Pods	Qmed	DRQM3G	59017804DRQM3GN7
Bamboo Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Bed Rope Ladder	Qmed	DRQM6A	59017804DRQM6AN4
Bio-gel heel protector	Qmed	DRIG0A0AAX01P	59017804DRIG0AJU
Breathable Kid Pillow	Qmed	DRQE3M	59017804DRQE3MMB
Butterfly Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Comfort Gel pillow	Qmed	MDQ0011	59017804MDQ0011EL
Comfort Seat cushion	Qmed	DRQE3L	59017804DRQE3LM9
Contour Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Corrective and Relieving Toe Wedge	Qmed	I205	59017804SLID1HNX
Diagnostic and corrective footwear	MEMO	DRMD	59017804DRMDQG
Duo Ball	Qmed Active	DRQM3K	59017804DRQM3KNF
ERGO Pillow	Qmed	DRQE3H	59017804DRQE3HLZ
Exercise Band	Qmed	DRQM3B	59017804DRQM3BMV
Finger Exerciser	Qmed Active	DRQM5A	59017804DRQM5AMZ
Flex Pillow	Qmed	DRQE3F	59017804DRQE3FLV
Foot Massage Mat	Qmed	DRQN3B	59017804DRQN3BN2
Forefoot Cushion	Qmed	I108	59017804DRID1RKJ
Gel exercise ball	Qmed	I207	59017804DRIEQ6
Hallucare	Qmed	I209	59017804DRIE0BJL
Hallucomfort	Qmed	DRQS3B	59017804DRQS3BNT
Halluduo	Qmed	I208	59017804DRIE0CJN
Hallufit	Qmed	I211	59017804DRIF0DJV
Hallustop	Qmed	DRIE0A1LAX01P	59017804DRIE0AJJ
Hallutrio	Qmed	DRQS3A	59017804DRQS3ANR
Hallux valgus protector	Qmed	I203	59017804SLID1FNT
Hallux valgus protector	Qmed	I206	59017804SLID1FNT
Hallux Valgus Toe Separator	Qmed	I201	59017804SLID1FNT
Hallux Valgus Toe Seprator	Qmed	I201	59017804SLID1FNT
Head Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Heel Shields	Qmed	I103	59017804SLID1FNT
Hot-Cold Pack	Qmed Care	DRQR3B	59017804DRQR3BNN
Kid Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Knee & Leg Spacer	Qmed	DRQM3J	59017804DRQM3JND
Lacrosse Ball	Qmed	DRQM3W	59017804DRQM3WP7
Lacrosse Duo Ball	Qmed	DRQM3U	59017804DRQM3UP3
Lumbar Half Roll Pillow	Qmed	DRQE3A	59017804DRQE3ALK
Lumbar Support Pillow	Qmed	DRQE0D	59017804DRQE3DLR
Massage Ball	Qmed	DRQM3H	59017804DRQM3HN9
MEMO gray insole	MEMO	DRM0	59017804DRM0PA
MEMO orange insole	MEMO	DRM1	59017804DRM1PC
Memory Mattress Topper	Qmed	DRQN3C	59017804DRQN3CN4
Metatarsal Pad	Qmed	I117	59017804DRID0KH

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Trade name of device	Brand name	Catalogue number	Basic UDI-DI
Metatarsal support	Qmed	I017	59017804DRID0KH
Orthopaedic heel pad	Qmed	I011-I016	59017804DRID0AJD
Orthopaedic insole	Qmed	I001 – I007	59017804DRID0AJD
Orthopedic footwear	MEMO	DRMO	59017804DRMOR6
Portable Hand Grip	Qmed	DRQM6D	59017804DRQM6DNA
Postoperative Shoe	Qmed	DRQI3P	59017804DRQI3PN5
Postoperative Shoe/Plaster Protection	Qmed	DRQI3R	59017804DRQI3RN9
Premium Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Profiled Traveling Pillow	Qmed	DRQE3K	59017804DRQE3KM7
Prophylactic and corrective footwear	MEMO	DRMB	59017804DRMBQC
Qmed Acupressure mat	Qmed	DRQN3A1	59017804DRQN3A1PQ
Qmed Acupressure Set	Qmed	DRQN3A	59017804DRQN3AMY
Qmed Bubble Mat - foldable massage mat for feet	Qmed	DRQN3H	59017804DRQN3HNE
Qmed Cocomat - natural acupressure set	Qmed	DRQN3G	59017804DRQN3GNC
Qmed Kinesiological tape	Qmed	DRQR5C, DRQR5D (set)	59017804DRQR5DNY
Qmed Mini roller	Qmed	DRQM6E	59017804DRQM6ENC
Qmed Standard Ball	Qmed	DRQM3N	59017804DRQM3NNM
Rehabilitation cushion with relieving gap	Qmed	DRQM6K	59017804DRQM6KNQ
Resistance Band	Qmed	DRQM6B	59017804DRQM6BN6
Resistance Loop Band Set	Qmed	DRQM3M	59017804DRQM3MNK
Safety Control Grip	Qmed	DRQM3A	59017804DRQM3AMT
SEAT & BACK bamboo cushion with cooling surface	Qmed	DRQE3P	59017804DRQE3PMH
Sensory path for children	Qmed	DRQN3F	59017804DRQN3FNA
Silicone Heel Pads Relieving Calcaneal Tuber	Qmed	I307	59017804DRIG0AJU
Slim Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Standard Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Standard Plus Pillow	Qmed	MDQ0011	59017804MDQ0011EL
Standard Roller	Qmed	DRQM3L	59017804DRQM3LNH
Swivel seat cushion	Qmed	DRQM6E	59017804DRQM6ENC
Therapy Roller	Qmed	DRQM3R	59017804DRQM3RNV
Thomsen splint	Qmed	I101	59017804DRIDQ4
Toe protector	Qmed	I204	59017804DRID1RKJ
Traveling Pillow	Qmed	DRQE0C	59017804DRQE0CLE
Vario Pillow	Qmed	DRQE3F	59017804DRQE3FLV
Ventilating silicone insoles	Qmed	I106	59017804DRID0RKF