MDH®

Qmed · MEMO

EB atitikties deklaracija

EU Declaration of Conformity

Gamintojo pavadinimas Manufacturer's name	mdh sp. z o.o.
Gamintojo adresas Manufacturer's address	ul. Maratońska 104, 94-007, Łódź, Lenkija (ES)
SRN (vienas registracijos numeris / Single Registration Number)	PL-MF-000011406
Klasifikacija Classification	I klasės rizika / Class I risk
Klasifikavimo taisyklė Rule of classification	1 taisyklė, VIII priedas, Reglamentas (ES) 2017/745
Atitikties vertinimo procedūra Conformity assessment route	II + III priedas, Reglamentas (ES) 2017/745

Ši atitikties deklaracija išduota išimtine mdh sp. z o.o. atsakomybe. Šiuo dokumentu pareiškiame, kad toliau nurodyti medicinos prietaisai (I priedas), pažymėti CE ženklu, atitinka Reglamento (ES) 2017/745 dėl medicinos prietaisų (MDR) reikalavimus ir atitinka toliau nurodytus standartus.

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

(taikomi standartai / applied standards)

I PRIEDAS / Annex I

Gaminio prekės pavadinimas Trade name of device	EMDN kodas EMDN code	Katalogo Nr. Catalogue number	Basic UDI-DI
ABS Gym Ball	V0899	DRQM3A	59017804DRQM3AMT
ABS Gym Ball – Peanut	V0899	DRQM3I0	59017804DRQM3I0Q7
Anti Snoring Pillow	V080399	DRQR3C	59017804DRQR3CNQ
Arch Pillow	V080399	DRQE3G	59017804DRQE3GLX
Baby Pillow	V080399	DRQE3C	59017804DRQE3CLP
Back Stretching Support	Y0599	DRQR3D	59017804DRQR3DNS
Balance Disc	V0899	DRQM3C	59017804DRQM3CMX
Balance Pods	V0899	DRQM3G	59017804DRQM3GN7
Bamboo Pillow	V080399	MDQ0011	59017804MDQ0011EL
Bed Rope Ladder	Y181803	DRQM3G0	59017804DRQM3G0PZ
Butterfly Pillow	V080399	MDQ0011	59017804MDQ0011EL
Comfort Gel pillow	V080399	MDQ0011	59017804MDQ0011EL
Comfort Seat cushion	V080399	DRQE3K	59017804DRQE3KM7
Contour Pillow	V080399	MDQ0011	59017804MDQ0011EL
Corrective toe wedge	Y061299	SLID1H	59017804SLID1HNX
Duo Ball	Y0599	DRQM3K	59017804DRQM3KNF
ERGO Pillow	V080399	DRQE3H	59017804DRQE3HLZ
Exercise Band	Y0599	DRQM3B	59017804DRQM3BMV
Finger Exerciser	Y0503	DRQM5A	59017804DRQM5AMZ
Flex Pillow	V080399	DRQE3I	59017804DRQE3IM3
Foot Massage Mat	Y0599	DRQN3B	59017804DRQN3BN2
Gel exercise ball	Y0599	DRIE	59017804DRIEQ6
Hallucare	Y061299	DRIE0B	59017804DRIE0BJL
Hallucomfort	Y061299	DRQS3B	59017804DRQS3BNT
Halluduo	Y061299	DRIE0C	59017804DRIE0CJN
Hallufit	Y061299	DRIF0D	59017804DRIF0DJV
Hallustop	Y061299	DRIE0A	59017804DRIE0AJJ
Hallutrio	Y061299	DRQS3A	59017804DRQS3ANR
Hallux valgus protector	Y061299	DRID1R	59017804DRID1RKJ
Hallux valgus toe separator	Y061299	SLID1F	59017804SLID1FNT
Head Pillow	V080399	MDQ0011	59017804MDQ0011EL
Hot-Cold Pack	M9001	DRQR3B	59017804DRQR3BNN
Kid Pillow	V080399	DRQE3L	59017804DRQE3LM9
Knee & Leg Spacer	V080399	DRQM3J	59017804DRQM3JND
Lacrosse Ball	Y0599	DRQM3W	59017804DRQM3WP7

Gaminio prekės pavadinimas Trade name of device	EMDN kodas EMDN code	Katalogo Nr. Catalogue number	Basic UDI-DI
Lacrosse Duo Ball	Y0599	DRQM3U	59017804DRQM3UP3
Lumbar Half Roll Pillow	V080399	DRQE3A	59017804DRQE3ALK
Lumbar support pillow (hard)	V080399	DRQE0D	59017804DRQE0DLG
Lumbar support pillow (soft)	V080399	DRQE3D	59017804DRQE3DLR
Massage Ball	Y0599	DRQM3H	59017804DRQM3HN9
MEMO Diagnostic and corrective footwear	Y061203	DRMD	59017804DRMDQG
MEMO gray insole	Y061203	DRM0	59017804DRM0PA
MEMO orange insole	Y061203	DRM1	59017804DRM1PC
MEMO Orthopedic footwear	Y061203	DRMO	59017804DRMOR6
MEMO Prophylactic and corrective footwear	Y061203	DRMB	59017804DRMBQC
Memory Mattress Topper	V080399	DRQN3C	59017804DRQN3CN4
Orthopaedic and prophylactic insole (metatarsal pad)	Y061299	DRID0	59017804DRID0KH
Orthopaedic insole	Y061203	DRID0A	59017804DRID0AJD
Portable Hand Grip	Y181803	DRQM6D	59017804DRQM6DNA
Postoperative Shoe	V0899	DRQI3P	59017804DRQI3PN5
Postoperative Shoe/Plaster Protection	V0899	DRQI3R	59017804DRQI3RN9
Premium Pillow	V080399	MDQ0011	59017804MDQ0011EL
Profiled Traveling Pillow	V080399	DRQE3J	59017804DRQE3JM5
Qmed Acupressure mat	V080399	DRQN3A1	59017804DRQN3A1PQ
Qmed Acupressure Set	V080399	DRQN3A	59017804DRQN3AMY
Qmed Bubble Mat - foldable massage mat for feet	Y0599	DRQN3H	59017804DRQN3HNE
Qmed Cocomat - natural acupressure set	V080399	DRQN3G	59017804DRQN3GNC
Qmed Kinesiological tape	M03030102	DRQR5C	59017804DRQR5CNW
Qmed Mini roller	V0899	DRQM6E	59017804DRQM6ENC
Qmed Standard Ball	Y0599	DRQM3N	59017804DRQM3NNM
Rehabilitation cushion with relieving gap	V080399	DRQM6K	59017804DRQM6KNQ
Resistance Band	Y0599	DRQM6B	59017804DRQM6BN6
Resistance Loop Band Set	Y0599	DRQM3M	59017804DRQM3MNK
SEAT & BACK bamboo cushion with cooling surface	V080399	DRQE3P	59017804DRQE3PMH
Sensory path for children	Y0599	DRQN3F	59017804DRQN3FNA
Slim Pillow	V080399	MDQ0011	59017804MDQ0011EL
Standard Pillow	V080399	MDQ0011	59017804MDQ0011EL
Standard Plus Pillow	V080399	MDQ0011	59017804MDQ0011EL
Standard Roller	Y0599	DRQM3L	59017804DRQM3LNH
Swivel seat cushion	V080399	DRQE3M	59017804DRQE3MMB
Therapy Roller	Y0599	DRQM3R	59017804DRQM3RNV
Thomsen splint	Y061299	DRID	59017804DRIDQ4
Traveling Pillow	V080399	DRQE0C	59017804DRQE0CLE
Vario Pillow	V080399	DRQE3F	59017804DRQE3FLV
Ventilating insoles	Y061203	DRID0T	59017804DRID0TKK

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