


EU DECLARATION OF CONFORMITY

| | | |
|------------------------------------|--|---|
| Manufacturer's name | mdh sp. z o. o. |  |
| Manufacturer's address | ul. Ks. W. Tymienieckiego 22/24, 90-349 Łódź, Poland | |
| 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 harmonized standards.

EN ISO 13485:2016
 EN ISO 14971:2012
 EN ISO 22523:2006
 PN-EN 15223-1:2017-02
 PN-EN 1041+A1:2013-12
 (applied harmonized standards)

MEMBER OF THE BOARD

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(company stamp)

Issue date: 10.06.2021

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 |
| 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 QAM04041 QAM04051 | XS-XL | 59017804QAM040F4 |

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|--|------------------|--|---------------|--------------------|
| 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 |
| Lumbo Medical lumbar bandage with sacrum pad | Meyra Medical | MY274201 | 1-6 | 59017804MY274201HB |

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| 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 | MY2762 | 1-4 | 59017804MY2762HF |
| Manu Medical wrist orthosis | Meyra Medical | MY2722 | 1-4 | 59017804MY2722H3 |
| Manu Meyra Comfort wrist orthosis | Meyra Medical | MY2761 | 1-6 | 59017804MY2761HD |
| 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 |
| ROM Knee Brace Covering Shin and Thing | Qmed | DRQI3S | Universal | 59017804DRQI3SNB |
| RUSH | Qmed | DRQI0N | Universal | 59017804DRQI0NMQ |

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| 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 |