

EU DECLARATION OF CONFORMITY

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| Manufacturer | mdh sp. z o. o. |  |
| Manufacturer's address | ul. Maratońska 104, 94-007, Łódź, Poland | |
| SRN (Single Registration Number) | PL-MF-000011406 | |
| Basic UDI-DI | 59017804DRQI7DMR | |
| Name of the Device | ACL RECOVER Functional knee brace | |
| Catalogue number | DRQI7D | |
| Classification | Class I | |
| Rule of classification | Rule I, Annex VIII, Regulation (EU) 2017/745 | |
| Conformity assessment route | Annex II+III, Regulation (EU) 2017/745 | |
| Intended use | Stabilises the knee joint, secures its ligaments after injury, surgery and when returning to sporting and professional activities. | |
| EMDN classification | Y061209 | |

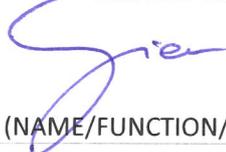
This declaration of conformity is issued under the sole responsibility of mdh sp. z o. o. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices and complies with the harmonized standards listed below.

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



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(COMPANY STAMP)

Date: 08.04.2024 Place: Łódź, Poland