EU DECLARATION OF CONFORMITY

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 he 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

MEMBER OF THE BOARD
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(NAME/FUNCTION/SIGNATURE)

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(COMPANY STAMP)

Date: 08.04.2024 **Place:** Łódź, Poland