


# EU DECLARATION OF CONFORMITY

<b>Manufacturer</b>	mdh sp. z o. o.	
<b>Manufacturer's address</b>	ul. Maratońska 104, 94-007, Łódź, Poland	
<b>SRN (Single Registration Number)</b>	PL-MF-000011406	
<b>Basic UDI-DI</b>	59017804DRQI7KN7	
<b>Name of the Device</b>	HIKE M4 Hinged knee brace	
<b>Catalogue number</b>	DRQI7K	
<b>Classification</b>	Class I	
<b>Rule of classification</b>	Rule I, Annex VIII, Regulation (EU) 2017/745	
<b>Conformity assessment route</b>	Annex II+III, Regulation (EU) 2017/745	
<b>Intended use</b>	A versatile knee brace with a wide range of therapeutic applications. Supports the treatment and rehabilitation process in the case of injuries and dysfunctions of the knee joint and its area.	
<b>EMDN classification</b>	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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Mariusz Gieralt



(NAME/FUNCTION/SIGNATURE)

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(COMPANY STAMP)

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