



# 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>	59017804DRQI7BMM	
<b>Name of the Device</b>	HIP BRACE Hip brace with flexion, extension and adduction adjustment range	
<b>Catalogue number</b>	DRQI7B	
<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>	Restriction of adduction and abduction and control of flexion and extension movement of the limb at the hip joint. Pressure relief and stabilisation of the joint.	
<b>EMDN classification</b>	Y061215	

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)

Date: 08.04.2024 Place: Łódź, Poland