

# 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>	59017804DRQF3IM8	
<b>Name of the Device</b>	UNO Hand orthosis stabilizing fingers	
<b>Accessory of the Device</b>	Additional stabilizer	
<b>Model (Catalogue number)</b>	DRQF3I	
<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	
<p>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.</p>		
<p><b>PN-EN ISO 13485:2016-04</b> <b>PN-EN ISO 14971:2020-05</b> <b>PN-EN ISO 15223-1:2022-01</b> <b>PN-EN ISO 20417:2021-10</b> <b>PN-EN ISO 22523:2007</b> (applied standards)</p>		
<p><b>MEMBER OF THE BOARD</b> Anetta Włodarczyk</p>  <p><b>MEMBER OF THE BOARD</b> Mariusz Gieralt</p>  <p>(NAME/FUNCTION/SIGNATURE)</p>		<p><b>mdh</b> sp. z o.o. 94-007 Łódź, ul. Maratońska 104 tel. 42 674 83 84 : <a href="http://www.mdh.pl">www.mdh.pl</a> NIP 7282295492 : REGON 472253652</p> <p>(COMPANY STAMP)</p>

Date: 17.10.2022 Place: Łódź, Polska