

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	59017804DRQF3HM6	
Name of the Device	DUO Hand orthosis stabilizing fingers	
Model (Catalogue number)	DRQF3H	
Classification	Class I	
Rule of classification	Rule I, Annex VIII, Regulation (EU) 2017/745	
Conformity assessment route	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>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)</p>		
<p>MEMBER OF THE BOARD Anetta Włodarczyk</p> <p></p> <p>MEMBER OF THE BOARD Mariusz Gierałt</p> <p></p> <p>(NAME/FUNCTION/SIGNATURE)</p>		<p>mdh sp. z o.o. 94-007 Łódź, ul. Maratońska 104 tel. 42 674 83 84 : www.mdh.pl NIP 7282295492 : REGON 472253652</p> <p>(COMPANY STAMP)</p>

Date: 17.10.2022 Place: Łódź, Polska