

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	

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)

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(COMPANY STAMP)

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