


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	59017804DRQI7GMX	
Name of the Device	AeroFit Ankle stabilisation brace	
Catalogue number	DRQI7G	
Classification	Class I	
Rule of classification	Rule I, Annex VIII, Regulation (EU) 2017/745	
Conformity assessment route	Annex II+III, Regulation (EU) 2017/745	
Intended use	Support for the treatment of ankle joint injuries: I° and II° sprains, ligamentous injuries. Stabilisation in instability of the ankle joint.	
EMDN classification	Y06120601	

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

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(NAME/FUNCTION/SIGNATURE)

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(COMPANY STAMP)

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