

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	59017804DRQJ0CM7	
Name of the Device	ActiveShoulder Shoulder and arm brace	
Catalogue number	DRQJ0C	
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	Postoperative treatment of fractures of the humeral head, scapular articular hollowing, dislocation of the shoulder joint. Degenerative changes of the shoulder joint and associated pain syndromes.	
EMDN classification	Y060621	

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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(NAME/FUNCTION/SIGNATURE)

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(COMPANY STAMP)

Date: 08.04.2024 Place: Łódź, Poland