

EU DECLARATION OF CONFORMITY

Manufacturer	mdh sp. z o. o.		
Manufacturer's address	ul. Maratońska 104, 94-007 Łódź, Poland (EU)		
SRN (Single Registration Number)	PL-MF-000011406		
Basic UDI-DI	59017804DRVIONNT		
Name of the Device	STAR Power wheelchair		
Catalogue number	DRVION	Models	BLU, ORANGE
Classification	Class I risk		
Rule of classification	Rule 13, Annex VIII, Regulation (EU) 2017/745		
Conformity assessment route	Annex II & III, Regulation (EU) 2017/745		
Intended use	Individual transport of disabled persons after spinal cord injuries, with cerebral palsy, with various injuries of the lower limbs, with neuromuscular diseases, after craniocerebral injuries, for geriatric patients.		
EMDN code	Y122127		

This EU Declaration of Conformity is issued under the sole responsibility of mdh Sp. z o. o. We declare that the medical device referred to above complies with the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 for medical devices, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment, the electromagnetic compatibility (EMC) requirements laid down in Directive 2014/30/EU, and the standards listed below.

PN-EN ISO 13485:2016-04	EN 12184:2022
PN-EN ISO 14971:2020-05	EN 62366-1:2015
PN-EN ISO 15223-1:2022-01	ASTM D4169:2022
PN-EN ISO 20417:2021-10	EN 60601-1-2:2015
PN-EN ISO 10993-1:2021-06	ISO/TR 24971:2020
EN ISO 10993-5:2009	EN ISO 10993-10:2013

(standards applied)

MEMBER OF THE BOARD

Anetta Włodarczyk



MEMBER OF THE BOARD

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(name/function/signature)

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(company stamp)

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