

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	59017804DRVIORP3	
Name of the Device	TWIST Power wheelchair	
Catalogue number	DRVIOR	
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 ISO 10993-1:2020
PN-EN ISO 14971:2020-05	EN ISO 10993-5:2009
PN-EN ISO 15223-1:2022-01	EN ISO 10993-10:2023
PN-EN ISO 20417:2021-10	EN ISO 10993-23:2021
PN-EN ISO 10993-1:2021-06	EN 60601-1-2:2015/A1:2021
EN 62366-1:2015/A1:2020	EN 60601-1:2006/A2:2021
EN 12184:2022	

(standards applied)

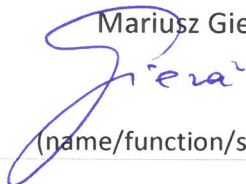
MEMBER OF THE BOARD

Anetta Włodarczyk



MEMBER OF THE BOARD

Mariusz Gierałt



(name/function/signature)

mdh sp. z o.o.

94-007 Łódź, ul. Maratońska 104
tel. 42 674 83 84 : www.mdh.pl
NIP 7282295492 : REGON 472253652

(company stamp)

Date: 17.07.2025 **Place:** Łódź, Poland (EU)