


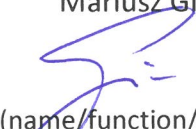
# EU DECLARATION OF CONFORMITY

<b>Manufacturer</b>	mdh sp. z o. o.	
<b>Manufacturer's address</b>	ul. Maratońska 104, 94-007 Łódź, Poland (EU)	
<b>SRN (Single Registration Number)</b>	PL-MF-000011406	
<b>Basic UDI-DI</b>	59017804DRVI00NV	
<b>Name of the Device</b>	MINI III Power wheelchair	
<b>Catalogue number</b>	DRVI00	
<b>Classification</b>	Class I risk	
<b>Rule of classification</b>	Rule 13, Annex VIII, Regulation (EU) 2017/745	
<b>Conformity assessment route</b>	Annex II & III, Regulation (EU) 2017/745	
<b>Intended use</b>	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.	
<b>EMDN code</b>	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.

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

(standards applied)

<b>MEMBER OF THE BOARD</b> Anetta Włodarczyk  <b>MEMBER OF THE BOARD</b> Mariusz Gierałt  (name/function/signature)	<b>mdh</b> sp. z o. o. 94-007 Łódź, ul. Maratońska 104 tel. 42 674 83 84 : www. mdh.pl NIP 7282295492 : REGON 472253652  (company stamp)
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Date: 01.04.2025 Place: Łódź, Poland (EU)