

EU DECLARATION OF CONFORMITY

Manufacturer	mdh sp. z o. o.	
Manufacturer's address	ul. Maratońska 104, 94-007 Łódź, Polska	
SRN (Single Registration Number)	PL-MF-000011406	
Basic UDI-DI	59017804DRVF15LX	
Name of the Device	TYTAN 2.0 Dual function lift	
Catalogue number	DRVF15	
Classification	Class I	
Rule of classification	Rule 13, Annex VIII, Regulation (EU) 2017/745	
Conformity assessment route	Annex II & III, Regulation (EU) 2017/745	
Intended use	Assistive product in hygiene activities for the disabled. Accessory - bathing sling.	
EMDN code	V08050303	

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 with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and for the 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

(standards applied)

PN-EN ISO 10993-1:2021-06
EN 60601-1-2:2007 + AC:2010
EN 60601-1:2015 + A1:2013
ISO 10535:2006

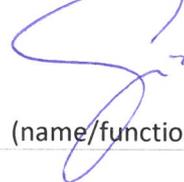
MEMBER OF THE BOARD

Anetta Włodarczyk



MEMBER OF THE BOARD

Mariusz Gierałt



(name/function/signature)

mdh sp. z o.o.

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(company stamp)

Date: 13.02.2025 **Place:** Łódź, Poland