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

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