

EU DECLARATION OF CONFORMITY

Manufacturer's name	mdh sp. z o. o.	
Manufacturer's address	ul. Maratońska 104, 94-007 Łódź, Poland	
SRN (Single Registration Number)	PL-MF-000011406	
Classification	Class I	
Rule of classification	Rule 1, Annex VIII, Regulation (EU) 2017/745	
Conformity assessment route	Annex II+III, Regulation (EU) 2017/745	

This declaration of conformity is issued under the sole responsibility of mdh sp. z. o. o. We hereby declare that the medical devices specified below (Annex I), marked CE, meet the provision of the Regulation (EU) MDR 2017/745 for medical devices and complies with required standards.

MEMBER OF THE BOARD

Anetta Włodarczyk



MEMBER OF THE BOARD

Mariusz Gierałt



(name/function/signature)

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Issue date: 01.01.2022

Place of issue: Łódź, Poland

Annex I

Trade name of device	Brand name	Catalogue number	Basic UDI-DI	Applied standards
FRANK 4-Wheel Steel Rollator	Vitea Care	VCBK221	59017804VCBKRG	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
FUN BABY Children rehabilitative car seat	Vitea Care	DRVR0B	59017804DRVR0BPG	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 ECE R44 (Regulation No 44)
GATO Multifunctional rehabilitative device	Vitea Care	DRVBP8	59017804DRVB8XP4	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
GRASS 4-Wheel Aluminium Rollator	Vitea Care	VCBK23242	59017804VCBKRG	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
HERO Manual standing wheelchair	Vitea Care	DRVL0F	59017804DRVL0FNS	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 1041+A1:2013-12 PN-EN 15223-1:2017-02
JUNIOR Children Rehabilitative Stroller	Vitea Care	DRVG0E	59017804DRVG0EMX	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
JUNIOR Plus Children Rehabilitative Stroller	Vitea Care	DRVG0J	59017804DRVG0JN9	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
Mobile Parapodium	Vitea Care	PJMP	59017804DRVCR9	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
MOBILUS LITE 4-Wheel Aluminum Rollator	Vitea Care	VCBK222B	59017804VCBKRG	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
PLATINUM Aluminium wheelchair	Vitea Care	VCWK9ASZ	59017804VCWK9ASZ97	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12

Annex I

Trade name of device	Brand name	Catalogue number	Basic UDI-DI	Applied standards
Static Parapodium Light	Vitea Care	PSL	59017804DRVBR7	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
SUPPORT Special Wheelchair Stabilizing Back and Head	Vitea Care	VCWK7CP	59017804VCWK7CPXA	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
TITANUM Aluminium wheelchair	Vitea Care	VCWK9AT	59017804VCWK9ATXN	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
TOM 3-Wheel Rollator	Vitea Care	VCBK521	59017804VCBKRG	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
TRIPLA 3-Function Walker	Vitea Care	VCBP0031	59017804VCBPRS	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN ISO 11199-1:2005 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
Tripod Cane	Vitea Care	VCBP0024	59017804VCBPRS	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
TRUST Standard Wheelchair with toilet function	Vitea Care	VCWK4T	59017804VCWK4TS9	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
UMBRELLA Children Rehabilitative Stroller	Vitea Care	DRVG0C	59017804DRVG0CMT	EN ISO 13485:2016 EN ISO 14971:2012 EN 12183:2014 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
WAVE Walker H4	Vitea Care	VCBP0032	59017804VCBPRS	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN ISO 11199-1:2005 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12