

EU DECLARATION OF CONFORMITY

Manufacturer	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 risk	Brand	VITEACARE
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)

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)

Issue date: 08.04.2020

Place of issue: Łódź, Poland (EU)

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
ACTIVE SPORT Aluminum wheelchair	Y122106	VCWK9AS	59017804VCWK9ASXL	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
ACTIVE SPORT LIGHT Aluminum wheelchair	Y122106	VCWK9ASL	59017804VCWK9ASL8B	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
ALEX 2-Wheel Rollator	Y1206	VCBK1	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
ALEX LIGHT Aluminium Rollator	Y1206	VCBK13253	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
AMBONA 4-Wheel Walker	Y1206	VCBK2A, VCBK2A_01	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
ARMPIT Crutches	Y1203	VCBP0041	59017804VCBP004LP	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Back support	Y0933	DRVF01	59017804DRVF01LL	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BACZUS RELAX Children Rehabilitative Stroller for all accessories of the stroller	Y122103	VCWR211R	59017804VCWR211R45	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BASIC PLUS Standard Wheelchair	Y122103	VCWK43BP	59017804VCWK43BP3U	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BASIC Standard Wheelchair	Y122103	VCWK43B	59017804VCWK43BUJ	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
Bath bench	Y0933	DRVW042; DRVW048	59017804DRVW04PF	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BILLY 3-Wheel Rollator	Y1206	VCBK5221	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BINGO Rehabilitative Chair	Y180918	DRVRXXAMBXCDP	59017804DRVRS7	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BLU Small shower stool	Y093303	VCTP0011	59017804VCTP0011XJ	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BOLA Walker with ball	Y1206	VCBP0032	59017804VCBPRS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 11199-1:2005 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
CAMELEON Aluminium wheelchair	Y122106	VCWK9AC	59017804VCWK9ACWL	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
CARTER Wheeled Walker	Y1206	VCBP0032	59017804VCBPRS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 11199-1:2005 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
COMBO Mobile Parapodium	Y180999	PJMC	59017804DRVNRX	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
COMFY Anti-bedsore cushion	V08030102	DRVT	59017804DRVTSB	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Commode Wheelchair	Y093399	VCWK2	59017804VCWK2RD	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
Commode chair	Y093399	DRVW01	59017804DRVW01P9	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 15223-1:2022-01 PN-EN ISO 12182:2012 PN-EN ISO 20417:2021-10
DUAL 2-Function Walker	Y1206	VCBP0031	59017804VCBPRS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 11199-1:2005 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Parapodium Dynamic	Y180999	PD	59017804DRVAR5	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Parapodium GYM Dynamic	Y180999	PDN	59017804DRVAR5	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
EDI High Rollator with Armrest	Y1206	VCBK223	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Elbow Crutches	Y1203	VCBP0042	59017804VCBP004LP	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
FELIZ Aluminium wheelchair	Y122103	VCWK9AL	59017804VCWK9ALX6	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
FIX Walker	Y1206	VCBP0032	59017804VCBPRS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 11199-1:2005 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
FLEXI LIGHT Aluminium wheelchair	Y122103	VCWK9AFL	59017804VCWK9AFL74	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Foldable Cane	Y1206	VCBP0022	59017804VCBP002LK	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
FORTE PLUS Standard Wheelchair	Y122106	VCWK42L	59017804VCWK42LV3	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
FRANK 4-Wheel Steel Rollator	Y1206	VCBK221	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
FUN BABY Children rehabilitative car seat	Y180999	DRVR0B	59017804DRVR0BPG	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 ECE R44 (Regulation No 44)
GATO Multifunctional rehabilitative device	Y180918	DRVB8X	59017804DRVB8XP4	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
GRASS 4-Wheel Aluminium Rollator	Y1206	VCBK23242	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
HERO Manual standing wheelchair	Y122103	DRVL0F	59017804DRVL0FNS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 20417:2021-10 PN-EN ISO 15223-1:2022-01
JUNIOR Children Rehabilitative Stroller	Y122103	DRVG0E	59017804DRVG0EMX	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
JUNIOR Plus Children Rehabilitative Stroller	Y122103	DRVG0J	59017804DRVG0JN9	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Parapodium, model Static	Y180999	Version: PSL PRO	59017804DRVZ2	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 21856:2023-01 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
MOBILUS LITE 4-Wheel Aluminum Rollator	Y1206	VCBK222B	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
NAVY 1 Light alloy wheelchair	Y122103	VCWK9AN	59017804VCWK9ANXA	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 PN-EN ISO 10993-1:2021-06 PN-EN 12183:2023-02
PREMIUM Wheelchair stabilizing back and head	Y122103	VCWK9CP	59017804VCWK9CRN	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Quadruped Cane	VITEACARE	VCBP0021	59017804VCBP002LK	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
RAINBOW Multifunctional rehabilitative device	Y180918	DRVBP8	59017804DRVB8AMN	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Raised Toilet Seat	Y180999	VCTP0031	59017804VCTP0031XQ	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
RECLINER Special-purpose wheelchair	Y122103	VCWK703	59017804VCWK703TU	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
RECLINER EXTRA Special-purpose wheelchair	Y122103	VCWK702	59017804VCWK702TS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
RECLINER LIGHT Special-purpose wheelchair	Y122103	VCWK701	59017804VCWK701TQ	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
RECLINER PLUS Special-purpose wheelchair	Y122103	VCWK7T	59017804VCWK7TSJ	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
REST Anti-bedsore Cushion (38x40x8 cm, 40x40x8 cm, 45x40x8 cm)	V08030102	DRVCT	59017804DRVCTPM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
ROCKY 4-Wheel Aluminum Rollator	Y1206	VCBK23231	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
ROCKY BASIC 4-Wheel Aluminum Rollator	Y1206	VCBK23231B	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
ROSE 4-Wheel Rollator with Footrest	Y1206	VCBK222T	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Rotor exerciser (Genesis, Genesis Plus)	Y0504	DRVF06	59017804DRVF0GLW	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Shower Seat	Y093303	VCTP0021	59017804VCTP0021XM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Small Shower Stool	Y093303	VCTP0011	59017804VCTP0011XJ	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
SOLID PLUS Standard Wheelchair	Y122103	VCWK43L	59017804VCWK43LV6	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
SPEEDY Multifunctional rehabilitative device	Y180918	DRVF04	59017804DRVF04AAB101PLC	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
SPRING Multifunctional rehabilitative device	Y180918	DRVF04	59017804DRVF04LS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
TITANUM Aluminium wheelchair	Y122103	VCWK9AT	59017804VCWK9ATXN	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
TOM 3-Wheel Rollator	Y1206	VCBK521	59017804VCBKRG	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
TRIPLA 3-Function Walker	Y1206	VCBP0031	59017804VCBPRS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 11199-1:2005 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
Tripod Cane	Y1203	VCBP0024	59017804VCBP002LK	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
TRUST Standard Wheelchair with toilet function	Y093399	VCWK4T	59017804VCWK4TS9	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
UMBRELLA Children Rehabilitative Stroller	Y122103	DRVG0C	59017804DRVG0CMT	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12183:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
WAVE Walker (H4)	Y1206	VCBP0032	59017804VCBPRS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 11199-1:2005 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
WHEELER Wheeled Walker	Y1206	VCBP0032	59017804VCBPRS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN ISO 12182:2012 PN-EN ISO 11199-1:2005 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10