


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 13, 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



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(company stamp)

Issue date: 01.03.2024

Place of issue: Łódź, Poland (EU)

Annex I

Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
ANTI-BEDSORE alternating pressure bubble mattress (including compressor)	V080701	VCM202	59017804VCMZV	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 12182:2012 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
ANTI-BEDSORE alternating pressure mattress (tubular structure, including compressor)	V080701	VCM502	59017804VCMZV	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 12182:2012 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
BUBBLE MASTER Anti-bedsore alternating pressure bubble mattress (including compressor)	V080701	VCM202G	59017804VCM202GKF	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 12182:2012 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
CAREBED Rehabilitation and care bed	V08060101	DRVOC	59017804DRVOCCLV	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 EN ISO 60601-1-2:2015+A1:2021 ISO 60601-2-52:2010+A1:2015 EN ISO 1041:2008+A1:2013 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 62366-1:2015
CRUISER II Power Wheelchair	Y122127	W4028 / DRV1	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
DAWID Mini Transport lifting device	V08050303	DRVF1	59017804DRVF1MS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 12182:2012 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
DE LUXE Power Wheelchair	Y122127	PCBL 1610/1810 / DRV1	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011

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DE LUXE LIFT Power Wheelchair	Y122127	PCBL 1620/1820 / DRVI	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
HERO Manual standing wheelchair	Y122127	DRVL0F	59017804DRVL0FNS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
HERO STAND UP Power Wheelchair	Y122127	DRVM6C	59017804DRVM6CPB	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
LIMBER Power Wheelchair	Y122127	W1018 / DRVI	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
MINI II Power wheelchair	Y122127	DRVK00	59017804DRVK00P7	EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 12184:2014 EN ISO 10993-5:2009 PN-EN ISO 20417:2021-10 PN-EN ISO 15223-1:2022-01 EN 60601-1-2:2015, IEC 62321-4 IEC 62321-4:2013+AMD1:2017 IEC 62321-5:2013 IEC 62321-7-2:2017 IEC 62321-6:2015 IEC 62321-8:2017 IEC 60601-1-2:2014
MODERN Power Wheelchair	Y122127	PCBL 1600/1800 / DRVI	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011

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Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
MODERN Power Wheelchair	Y122127	PCBL 1630/1830 / DRVI	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
MULTIPLUS Power wheelchair	Y122127	DRVIOM	59017804DRVIOMNR	EN ISO 13485:2016 EN ISO 14971:2019 PN-EN 12182:2012 PN-EN ISO 11199-2:2005 PN-EN ISO 12184:2014-07 PN-EN ISO 20417:2021-10 PN-EN ISO 15223-1:2022-01 EN ISO 60601-1:2006+A12:2014 IEC 62321:2008 IEC 62321-4:2013 IEC 62321-5:2013 EN ISO 10993-5:2009 EN 55014-2:1997/A2:208 EN 55014-1:2006/A2:2011
RIDER II Power Wheelchair	Y122127	W4025	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
SAMSON Transport lifting device	V08050303	DRVF02	59017804DRVF02LN	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 12182:2012 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
SCRUBBY Power Wheelchair	Y122127	PCBL1220/1420	59017804DRVIRM	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
SIMPLY BUBBLE Anti-bedsore alternating pressure mattress (including compressor)	V080701	VCM202B	59017804VCM202BK5	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 12182:2012 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10
TUBE LIGHT Anti-bedsore alternating pressure mattress (tubular structure, including compressor)	V080701	VCM502F	59017804VCMZV	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10

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Trade name of device	EMDN Code	Catalogue number (Type)	Basic UDI-DI	Applied standards
W4026 Mini Power wheelchair (scooter type)	Y122127	DRVK0L	59017804DRVK0LNZ	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011
W459 Power Wheelchair models: CROSS SMART EASY GO	Y122127	DRVK0P	59017804DRVK0PP9	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2023-02 PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11 PN-EN 60601-1:2011