


# EU DECLARATION OF CONFORMITY

<b>Manufacturer's name</b>	mdh sp. z o. o.	
<b>Manufacturer's address</b>	ul. Maratońska 104, 94-007 Łódź, Poland	
<b>SRN (Single Registration Number)</b>	PL-MF-000011406	
<b>Classification</b>	Class I	
<b>Rule of classification</b>	Rule 13, Annex VIII, Regulation (EU) 2017/745	
<b>Conformity assessment route</b>	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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**Issue date:** 01.08.2022

**Place of issue:** Łódź, Poland

## Annex I

Trade name of device	Brand name	Catalogue number	Basic UDI-DI	Applied harmonized standards
ANTI-BEDSORE alternating pressure bubble mattress including compressor	VITEACARE	VCM202	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
ANTI-BEDSORE alternating pressure mattress of tubular structure including compressor	VITEACARE	VCM502	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
BUBBLE MASTER Anti-bedsore alternating pressure bubble mattress including compressor	VITEACARE	VCM202G	59017804VCM202GKF	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
CRUISER II Power Wheelchair	VITEACARE	W4028	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
DAVID Transport lifting device	VITEACARE	DRVF1	59017804DRVF1MS	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
DE LUXE Power Wheelchair	VITEACARE	PCBL1610/1810	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
DE LUXE LIFT Power Wheelchair	VITEACARE	PCBL1620/1820	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
EASY Power Wheelchair	VITEACARE	W1032	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
HERO Manual standing wheelchair	VITEACARE	DRVL0F	59017804DRVL0FNS	PN-EN ISO 13485:2016-04 PN-EN ISO 14971:2020-05 PN-EN 62304:2010 PN-EN 12184:2014-07

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				PN-EN ISO 15223-1:2022-01 PN-EN ISO 20417:2021-10 PN-EN 60601-1-2:2015-11
HERO STAND UP Power Wheelchair	VITEACARE	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
LIMBER Power Wheelchair	VITEACARE	W1018	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
MINI II Power wheelchair	VITEACARE	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	VITEACARE	PCBL1600/1800	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
MULTIPLUS Power wheelchair	VITEACARE	DRVI0M	59017804DRVI0MNR	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	VITEACARE	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

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Trade name of device	Brand name	Catalogue number	Basic UDI-DI	Applied harmonized standards
SAMSON Transport lifting device	VITEACARE	DRVF02	59017804DRVF02LN	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
SCRUBBY Power Wheelchair	VITEACARE	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
SIMPLY BUBBLE Anti-bedsore alternating pressure mattress including compressor	VITEACARE	VCM202B	59017804VCM202BK5	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
TUBE MASTER Anti-bedsore alternating pressure mattress of tubular structure including compressor	VITEACARE	VCM502D	59017804VCM502DKW	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
TUBE LIGHT Anti-bedsore alternating pressure mattress of tubular structure including compressor	VITEACARE	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
W4026 Mini	VITEACARE	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