


EU DECLARATION OF CONFORMITY

Manufacturer's name	mdh sp. z o. o.	
Manufacturer's address	ul. Ks. W. Tymienieckiego 22/24, 90-349 Łódź, Poland	
Classification	Class I	
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 harmonized standards.

MEMBER OF THE BOARD

Anetta Włodarczyk



MEMBER OF THE BOARD

Mariusz Gierałt



(name/function/signature)

mdh sp. z o.o.

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(company stamp)

Issue date: 01.05.2021

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	Vitea Care	VCM202, VCM202B	59017804VCMZV	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
ANTI-BEDSORE alternating pressure mattress of tubular structure including compressor	Vitea Care	VCM502	59017804VCMZV	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
BUBBLE MASTER Anti-bedsore alternating pressure bubble mattress including compressor	Vitea Care	VCM202G	59017804VCMZV	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
CRUISER II Power Wheelchair	Vitea Care	W4028	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
DAVID Transport lifting device	Vitea Care	DRVF1	59017804DRVF1MS	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
DE LUXE Power Wheelchair	Vitea Care	PCBL1610/1810	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
DE LUXE LIFT Power Wheelchair	Vitea Care	PCBL1620/1820	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
EASY Power Wheelchair	Vitea Care	W1032	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11

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HERO STAND UP Power Wheelchair	Vitea Care	DRVM6C	59017804DRVM6CPB	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
LIMBER Power Wheelchair	Vitea Care	W1018	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
MODERN Power Wheelchair	Vitea Care	PCBL1600/1800	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
RIDER II Power Wheelchair	Vitea Care	W4025	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
SAMSON Transport lifting device	Vitea Care	DRVF02	59017804DRVF02LN	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
SCRUBBY Power Wheelchair	Vitea Care	PCBL1220/1420	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
SIMPLY BUBBLE Anti-bedsore alternating pressure mattress including compressor	Vitea Care	VCM202B	59017804VCMZV	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
TUBE LIGHT Anti-bedsore alternating pressure mattress of tubular structure including compressor	Vitea Care	VCM502F	59017804VCMZV	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12

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TUBE MASTER Anti-bedsore alternating pressure mattress of tubular structure including compressor	Vitea Care	VCM502D	59017804VCMZV	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 12182:2012 PN-EN 60601-1:2011 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12
W4026 Mini	Vitea Care	DRVKOL	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11
WAY Power add-on device	Vitea Care	DRVKOM	59017804DRVIRM	EN ISO 13485:2016 EN ISO 14971:2012 PN-EN 62304:2010 PN-EN 12184:2014-07 PN-EN 15223-1:2017-02 PN-EN 1041+A1:2013-12 PN-EN 60601-1-2:2015-11