


EU DECLARATION OF CONFORMITY

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|---|---|---|
| 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 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

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(name/function/signature)

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(company stamp)

Issue date: 01.01.2022

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 | 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 |