

**EU DECLARATION OF CONFORMITY No. DPDOC/7/VM**

*Elaborated in accordance with Annex IV of the Medical Device Regulation 2017/745 of EU Parliament and the Council*

MANUFACTURER: **DEVOLPE s.r.o.**

REGISTERED TRADE MARK: **DEVOLPE**

REGISTERED ADDRESS: **Nám. 14. října 1307/2, Prague 5, 150 00, Czech Republic**

UDI-ID: **859420959VMSWJ (SOLO- CHAMBER), 859420959VMPWC (POLI-CHAMBER)**

NAME OF THE DEVICE: **VACUUM MATTRESS**

MODELS: **VACUUM MATTRESS SOLO-CHAMBER, VACUUM MATTRESS POLI-CHAMBER**

CATALOG CODE: **VM/01/VMSDP (SOLO- CHAMBER), VM/02/VMPDP (POLI-CHAMBER)**

LOT NO: **CZR23001VMS (SOLO- CHAMBER), CZR23001VMP (POLI-CHAMBER)**

RISK CLASS: **Class I**

**According to Rule 1 of the Chapter III (Classification rules) namely non-invasive device of Annex VIII of the Medical Device Regulation 2017/745 of EU Parliament and the Council**

**MANUFACTURER HEREBY DECLARES:**

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| - that the above specified medical device represents <b>risk class I</b> device according to the requirements of Annex IX of the Medical Device Regulation 2017/745 of EU Parliament and the Council.   |
| - that the product complies with the all applicable provisions of Annexes of the Medical Device Regulation 2017/745 of EU Parliament and the Council concerning medical devices and the product`s conformity is applicable to conformity procedure of the abovementioned legislation. |

**FURTHER IT IS DECLARED THAT THE PRODUCT HAS BEEN:**

designed, developed, manufactured and tested in accordance with all applicable standards mentioned below and by using a quality management system according to DIN EN ISO 13485:2016 for medical devices. The above mentioned products have met the requirements of the medical device for placing CE marking and ISO 13485:2016 for medical devices.
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The current declaration of conformity has been drafted in accordance with the requirements of the Annexes IV and V of the Medical Device Regulation 2017/745 of EU Parliament and the Council.

**STANDARDS APPLIED TO THE PRODUCT:**

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| - ISO 13485:2016 Quality management system for medical device   |
| - EN 1865-1:2010-12 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment |
| - EN 1041:2008 + A1: 2013 information supplied by manufacturer  |
| - EN ISO 15223:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied             |
| - EN 14971:2012 Medical devices - Application of risk management to medical devices   |

**AFFIRMED BY THE MANUFACTURER`s REPRESENTATIVE**

**In Prague, on February 3, 2023**



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