DEVOLPE MEDICAL

CE

EU DECLARATION OF CONFORMITY No. DPDOC/8/VS

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: **Nam. 14. rijna 1307/2, Prague 5, 150 00, Czech Republic**
UDI-ID: **859420959LVSSTT (LEG VS SOLO- CHAMBER), 859420959LVSPTM (LEG VS POLI-CHAMBER), 859420959AVSSRE (ARM VS SOLO- CHAMBER), 859420959AVSPR8 (ARM VS POLI- CHAMBER), 859420959ANVSSQH (ANKLE VS SOLO- CHAMBER), 859420959ANVSPQB (ANKLE VS POLI- CHAMBER), 859420959HVSV7 (HEAD VACUUM IMMOBILIZER)**
NAME OF THE DEVICE: **VACUUM SPLINTS**
MODELS: **ARM VACUUM SPLINT SOLO-CHAMBER, ARM VACUUM SPLINT POLI-CHAMBER, LEG VACUUM SPLINT SOLO-CHAMBER, LEG VACUUM SPLINT POLI-CHAMBER, ANKLE VACUUM SPLINT SOLO-CHAMBER, ANKLE VACUUM SPLINT POLI-CHAMBER, HEAD VACUUM IMMOBILIZER**
CATALOG CODE: **VS/01/LVSSDP (LEG VS SOLO- CHAMBER), VS/02/LVSPDP (LEG VS POLI-CHAMBER), VS/03/AVSSDP (ARM VS SOLO- CHAMBER), VS/04/AVSPDP (ARM VS POLI- CHAMBER), VS/05/ANVSSDP (ANKLE VS SOLO- CHAMBER), VS/06/ANVSPDP (ANKLE VS POLI- CHAMBER), VS/07/HVSDP (HEAD VACUUM IMMOBILIZER)**
LOT NO: **CZR23001LVSS (LEG VS SOLO- CHAMBER), CZR23001LVSP (LEG VS POLI-CHAMBER), CZR23001AVSS (ARM VS SOLO- CHAMBER), CZR23001AVSP (ARM VS POLI- CHAMBER), CZR23001ANVSS (ANKLE VS SOLO- CHAMBER), CZR23001ANVSP (ANKLE VS POLI- CHAMBER), CZR23001HVS (HEAD VACUUM IMMOBILIZER)**
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:

- that the above specified medical device represents **risk class I** 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.

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:

- ISO 13485:2016 Quality management system for medical device
- 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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