

EU DECLARATION OF CONFORMITY No. DPDOC/2/DS

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: **859420959DS2Z & 859420959MB2S**

NAME OF THE DEVICE: **STRETCHER BASE SUPPORT**

MODELS: **DUO-SLIDER & MONO-BASE**

CATALOG CODE: **SBS/02/DSDP (DUO-SLIDER) & SBS/01/DSDP (MONO-BASE)**

LOT NO: **CZR23001DS (DUO-SLIDER) & CZR23001MB (MONO-BASE)**

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 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.
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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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| <ul style="list-style-type: none">- ISO 13485:2016 Quality management system for medical device- EN 1789:2007+A1:2010 Medical vehicles and their equipment - Road ambulances- EN 1865-5:2010-12 Patient handling equipment used in road ambulances - Part 5: Stretcher Support- EN 1041:2008 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- |
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AFFIRMED BY THE MANUFACTURER`s REPRESENTATIVE

In Prague, on February 3, 2023



Devolpe s.r.o.
nám. 14. října 1307/2
150 00 Prague 5, Czech Republic
ID: 09776885, TIN: CZ09776885
info@devolpe.com | www.devolpe.com