

EU DECLARATION OF CONFORMITY No. DPDOC/3/ESCT

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**

OWNED TRADEMARK: **DEVOLPE**

UDI-ID: **859420959ESCTQD (ESCACHAIR WITH STAIR BELTS), 859420959ESCWTQF (ESCACHAIR WITHOUT STAIR BELTS)**

NAME OF THE DEVICE: **FOLDABLE PATIENT TRANSFER CHAIR**

MODELS: **ESCACHAIR WITH STAIR BELTS, ESCACHAIR WITHOUT STAIR BELTS**

CATALOG CODE: **FPTC/02/ESCDP & FPTC/01/ESCDP**

LOT NO: **CZR23001ESC & CZR23001ESCWT**

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.

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 1789:2007+A1:2010 Medical vehicles and their equipment - Road ambulances |
| - EN 1865-1:2010-12 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment (for all kinds of chairs) |
| - EN 1865-4:2010-12 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair |
| - 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



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