

## EU - Declaration of Conformity



We, **X-CEN-TEK GmbH & Co. KG**, Westerburger Weg 30 - D-26203 Wardenburg, declare under our sole responsibility that the medical devices of the product group

### ***PAX Rescue & Transport Systems***

**Basic UDI-DI: 426074548 016018020019 MJ**

complies with the relevant provisions of Regulation (EU) 2017/745 (MDR) on medical devices and, where applicable, other relevant Union legislation

#### The product group includes the following medical devices

| Commercial name            | Article No. | Commercial name                            | Article No. |
|----------------------------|-------------|--|-------------|
| <b>PAX RTS - Summer</b>    | 275500404   | <b>PAX RTS - Winter</b>                    | 275510404   |
| <b>PAX RTS - 4 Seasons</b> | 276780801   | <b>PAX Patient Soft Carrier with Cover</b> | 123520101   |

**Intended use of the product group:** Rescue and transport of injured and sick persons

According to Annex VIII, Rule 1 MDR, all devices in the product group are class 1 medical devices and the applicable essential safety and performance requirements according to Annex I MDR are fulfilled. A conformity assessment procedure according to Annex II & III MDR has been carried out.

**Applicable harmonized standards**, national standards, or other regulatory documents:

**EN ISO 13485:2016** – Medical devices – Quality management systems – Requirements for regulatory purposes

**EN ISO 14971:2019** – Medical devices – Application of risk management to medical devices

**EN 1865-1:2010** – Patient handling equipment used in road ambulances

This EU Declaration of Conformity is  
valid until **25<sup>th</sup> of May 2023**

*Nils-Lasse Schneider*

Wardenburg, the 25<sup>th</sup> of May 2022

Dr. Nils-Lasse Schneider

PRRC according to Art.15 MDR

**Manufacturers SRN: DE-MF-000009521**

|   |                              |                           |                              |                             |
|---|------------------------------|---------------------------|------------------------------|-----------------------------|
| Version 1.0                                     | BasDok erstellt: TC-05.04.21 | Freigabe QMB: TB-07.04.21 | Dok erstellt: TC             | Freigabe VP: NLS-25.05.2022 |
| Datei: PAX CE KE-EN RTS 05-22                   |                              |                           | Anlage: 28.04.21             | Stand: 25.05.2022           |
| Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg |                              |                           | QM-System nach EN 13485:2016 | Seite 1 von 1               |