

## 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 Spineboard harness system - black</b> | 102001103   |                 |             |

**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** – Medical devices – Quality management systems – Requirements for regulatory purposes

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

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

This EU Declaration of Conformity is  
valid until **25.05.2025**

*Nils-Lasse Schneider*

Wardenburg, the 25.05.2024

Dr. Nils-Lasse Schneider  
PRRC according to Art.15 MDR

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

|   |                                |                             |                             |                               |
|---|--------------------------------|-----------------------------|-----------------------------|-------------------------------|
| Version 1.0                                     | BasDok erstellt: TC-05.04.2021 | Freigabe QMB: TB-07.04.2021 | Dok erstellt: TC            | Freigabe VP: NLS - 25.05.2024 |
| Datei: PAX CE KE-EN SpinebGS 05-24.docx         |                                |                             | Anlage: 28.04.2021          | Stand: 25.05.2024             |
| Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg |                                |                             | QM-System nach EN ISO 13485 | Seite 1 von 1                 |