# 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.** |
| **PAX Rescue-BOA** | 118171908 | **PAX Rescue-BOA Military** | 131590421 |

**Intended use of the product group**: Evacuation of patients / persons in time-critical situations under stabilization of the cervical and thoracic spine

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 **25th of May 2023**

Nils-Lasse Schneider

Wardenburg, the 17th of February 2023

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

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