

# 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 Rescue-Bag RTS Air</b> Version Air Zermatt	146110801	<b>PAX Rescue-Bag RTS AIR - warming blanket</b>	276921908
<b>PAX Rescue-Bag RTS AIR - harness</b>	272674201		

**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**

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Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1