

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-Bag RTS Air Version Air Zermatt	146110801	PAX Rescue-Bag RTS AIR - warming blanket	276921908
PAX Rescue-Bag RTS AIR - harness	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 13485:2016 – 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 2022**

Nils-Lasse Schneider

Wardenburg, the 25th of May 2021

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-04.02.22
Datei: PAX CE KE-EN RTS Air AZ 02-22			Anlage: 28.04.21	Stand: 04.02.22
Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN 13485:2016	Seite 1 von 1