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 Carrying Sheet basic	104490201	**PAX Rescue Sheet with anti slip device L**	102260201
PAX Rescue Sheet XL with weight indication	102270201	**PAX Carrying Sheet XXL 400 kg**	101820201

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 2023**

Nils-Lasse Schneider

Wardenburg, the 25th of May 2022

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

Manufacturers SRN: DE-MF-000009521