

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
PAX Immobilization-hand loop	12920		

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 – 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 **25.05.2026**

Nils-Lasse Schneider

Wardenburg, 25.05.2025

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

Manufacturers SRN: DE-MF-000009521

Version 1.1	BasDok erstellt: TC-05.04.21	Freigabe QMB: TC-10.08.2023	Dok erstellt: TC	Freigabe VP: NLS – 23.05.2025
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Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1