

# 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 Eva Fix System</b>	13657S Eva Fix		
<b>Eva Fix - Chest fixation left</b>	142660209	<b>Eva Fix - Chest fixation right</b>	142670209
<b>Eva Fix - Leg fixation left</b>	142680208	<b>Eva Fix - Leg fixation right</b>	142690208

**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

Version 1.0	BasDok erstellt: TC-05.04.2021	Freigabe QMB: TB-07.04.2021	Dok erstellt: TC	Freigabe VP: NLS - 25.05.2024
Datei: PAX CE KE-EN EvaFix 05-24.docx			Anlage: 28.04.2021	Stand: 25.05.2024
Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1