

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 Eva Fix System	13657S Eva Fix		
Eva Fix - Chest fixation left	142660209	Eva Fix - Chest fixation right	142670209
Eva Fix - Leg fixation left	142680208	Eva Fix - Leg fixation right	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 13485:2016 – 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

Version 1.0	BasDok erstellt: TC-05.04.21	Freigabe QMB: TB-07.04.21	Dok erstellt: TC	Freigabe VP: NLS-25.05.2022
Datei: PAX CE KE-EN EvaFix 05-22			Anlage: 28.04.21	Stand: 25.05.2022
Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1