

## 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 Vacuum splints***

**Basis UDI-DI: 426074548 0169013013019 YU**

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 Vacuum splint - rec arm	162025210	PAX Vacuum splint - Reilly - leg	162295210
PAX Vacuum splint - rec joint	162035210	PAX Vacuum splint - Reilly - arm	162305210
PAX Vacuum splint - rec leg	162265210	PAX Vacuum splint - Reilly - ankle	162285210
PAX Vacuum splint - forearm	155535210	PAX Vacuum splint - leg	155545210
PAX Vacuum splint - elbow	155555210		

**Intended use of the product group:** immobilization for injuries and illnesses

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 **25<sup>th</sup> of May 2023**

*Nils-Lasse Schneider*

Wardenburg, the 25<sup>th</sup> 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-25.05.22
Datei: PAX CE KE-EN VakSchie 05-22		Anlage: 28.04.21		Stand: 25.05.22
Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1