

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 – 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 **25th of May 2024**

Nils-Lasse Schneider

Wardenburg, the 25th of May 2023

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-25.05.2023
Datei: PAX CE KE-EN VakSchie 05-23		Anlage: 28.04.2021		Stand: 25.05.2023
Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1