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 **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