

# 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 accessories***

**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 Fixation Strap Set - Vacuum Splint - elbow	274731110	PAX Fixation Strap Set - Vacuum Splint - rec	165121110
PAX Fixation Strap Set - Vacuum Splint - leg	274751110	PAX Fixation Strap Set - Vacuum Splint - forearm	274741110
PAX Fixation Strap Set - Vacuum mattress	157004200	Pax Handle Set - Vacuum mattress - (Set of 10)	156990008
PAX Head Fixation Set - Vacuum mattress - (Set of 10)	274981508	Pax Handle Set - Vacuum mattress - (Set of 2)	162420008
PAX Head Fixation - Vacuum mattress	160881508	PAX Vacuum pump - Hand	270890003
PAX Vacuum valve with adapter for fingertip	274270000	PAX Vacuum pump - Foot	273130003
PAX Vacuum valve - mattress and splint	26868	PAX Repair Patch Vacuum	15751000
PAX safety loop Vacuum valve	268790303	PAX Adapter T-piece for head fixation	164244203

**Intended use of the product group:** Accessories for Vacuum products for 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

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 VakZub 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