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 Fixation Strap Set TPU- Vacuum mattress	283643000	**Pax Handle Set - Vacuum mattress -** (Set of 2)	162420008
PAX Head Fixation Set - Vacuum mattress - (Set of 10)	274981508	**PAX Vacuum pump - Hand**	270890003
PAX Head Fixation - Vacuum mattress	160881508	**PAX Vacuum pump – Hand S**	286320003
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 – Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971 – Medical devices – Application of risk management to medical devices

This EU Declaration of Conformity is
valid until **25.05.2025**

Nils-Lasse Schneider

Wardenburg, 25.05.2024

Dr. Nils-Lasse Schneider
PRRC according to Art.15 MDR

Manufacturers SRN: DE-MF-000009521