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 mattresses

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 mattress - I-Mat - handles	155165210	**PAX Vacuum mattress - Ergo-Mat - handles**	155135210
PAX Vacuum mattress - Mummy-Mat - handles	155155210	**PAX Vacuum mattress - Ergo-Mat - handlebar**	155125210
PAX Vacuum mattress - Mummy-Mat - handle bar	155145210	**PAX Vacuum mattress - Ergo-Mat - handles & head fixation**	160875210
PAX Vacuum mattress - Mummy-Mat - plus - handles & head fixation	277025210	**PAX Vacuum mattress - Ergo-Mat - handlebar & head fixation**	162415210
PAX Vacuum mattress - AR 1	160205301	**PAX Vacuum mattress - Ergo-Mat - handles & head fixation - Bayern**	276575210
PAX Vacuum mattress - AR 2 (grey version)	155585210	**PAX Vacuum mattress - AR 2** (red version)	155585201
		PAX Vacuum mattress - AR 3	277095301

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 21.11.2024

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

Manufacturers SRN: DE-MF-000009521