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 Temperature Management Systems

Basic UDI-DI: 426074548 016020013019 J7

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 – Ergo-Mat – handles – TMS	285495210	**PAX Vacuum mattress – Ergo-Mat – handles – tactical – TMS**	285615203
PAX Vacuum mattress – I-Mat – handles – TMS	292205210	**PAX Vacuum mattress – I-Mat – handles – tactical – TMS**	292216803
PAX Vacuum mattress – Mummy-Mat – handles – TMS	283605210	**PAX Vacuum mattress – AR 1 – TMS**	285265301
PAX Vacuum mattress – AR 2 – TMS	291465301	**PAX Vacuum mattress – AR 3 – TMS**	291435301

Intended use of the product group: Vacuum mattresses for immobilisation in the event of injuries and illnesses during treatment and transport, with an integrated temperature management system to enhance patient comfort.

According to Annex VIII, Rule 1 & 13 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 **25.05.2027**

Wardenburg, 22.05.2026

Dr. med. Thomas Castner
Dep. PRRC according to Art.15 MDR

Manufacturers SRN: DE-MF-000009521