

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 – Mummy-Mat – handles – TMS | 283605210 |
| PAX Vacuum mattress – AR 1 – TMS | 285265301 | PAX Vakuummattmatratze - I-Mat – handles – TMS | 292205210 |
| 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**

Dr. Thomas Castner

Wardenburg, 20.03.2026

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

Manufacturers SRN: DE-MF-000009521

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|---|--------------------------------|-----------------------------|-----------------------------|------------------------------|
| Version 1.1 | BasDok erstellt: TC-05.04.2021 | Freigabe QMB: TC-10.08.2023 | Dok erstellt: ME | Freigabe VP: TC – 20.03.2026 |
| Datei: PAX CE KE-EN PG VM-TMS 03-26.docx | | | Anlage: 09.03.2026 | Stand: 20.03.2026 |
| Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg | | | QM-System nach EN ISO 13485 | Seite 1 von 1 |