

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 Warming blanket - THX | 278165201 | PAX Warming blanket – THX 2.0 | 284015201 |
| PAX Power Pack – 60/2 | 283160000 | PAX Baby Shell – TMS | 287171908 |

Intended use of the product group: Temperature management systems to maintain heat and increase patient comfort during care and transport.

According to Annex VIII, Rule 1&13 MDR, all devices in the product group are class 1 medical devices and the applicable general 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 60068-2-31 – Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks

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 **25.05.2027**

Wardenburg, 22.05.2026

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 - 22.05.2026 |
| Datei: PAX CE KE-EN PG WaeDe 05-26.docx | | | Anlage: 18.05.2026 | Stand: 22.05.2026 |
| Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg | | | QM-System nach EN ISO 13485 | Seite 1 von 1 |