

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 **25.05.2026**

Nils-Lasse Schneider

Wardenburg, 25.05.2025

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

Manufacturers SRN: DE-MF-000009521

Version 1.1	BasDok erstellt: TC-05.04.2021	Freigabe QMB: TC-10.08.2023	Dok erstellt: TC	Freigabe VP: NLS – 25.05.2025
Datei: PAX CE KE-EN PG WaeDe 05-25.docx			Anlage: 02.07.2022	Stand: 25.05.2025
Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1