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 **25.05.2025**

Nils-Lasse Schneider

Wardenburg, 12.02.2025

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

Manufacturers SRN: DE-MF-000009521