

# 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. |
|----------------------------------|-------------|--------------------------------------|-------------|
| <b>PAX Warming blanket - THX</b> | 278165201   | <b>PAX Warming blanket – THX 2.0</b> | 284015201   |
| <b>PAX Power Pack – 60/2</b>     | 283160000   |                                      |             |

**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 60601-1-12** – Medical electrical Equipment

**EN 62366-1** – Application of usability engineering to medical devices

**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, the 25.05.2024

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

**Manufacturers SRN: DE-MF-000009521**

|   |                                |                             |                             |                               |
|---|--------------------------------|-----------------------------|-----------------------------|-------------------------------|
| Version 1.0                                     | BasDok erstellt: TC-05.04.2021 | Freigabe QMB: TB-07.04.2021 | Dok erstellt: TC            | Freigabe VP: NLS – 25.05.2024 |
| Datei: PAX CE KE-EN PG WaeDe 05-24.docx         |                                |                             | Anlage: 02.07.2022          | Stand: 25.05.2024             |
| Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg |                                |                             | QM-System nach EN ISO 13485 | Seite 1 von 1                 |