# 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 | | |

**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 **25.05.2024**

Nils-Lasse Schneider

Wardenburg, the 05.01.2024

Dr. Nils-Lasse Schneider

PRRC according to Art.15 MDR

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