

## 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		

**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<sup>th</sup> of May 2024**

*Nils-Lasse Schneider*

Wardenburg, the 25<sup>th</sup> of May 2023

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

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

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Datei: PAX CE KE-EN PG WäDe 05-23			Anlage: 02.07.2022	Stand: 25.05.2023
Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1