

# 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 Vacuum mattresses**

**Basis UDI-DI: 426074548 0169013013019 YU**

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 Vacuum mattress - I-Mat</b> - handles	155165210	<b>PAX Vacuum mattress - Ergo-Mat</b> - handles	155135210
<b>PAX Vacuum mattress - Mummy-Mat</b> - handles	155155210	<b>PAX Vacuum mattress - Ergo-Mat</b> - handlebar	155125210
<b>PAX Vacuum mattress - Mummy-Mat</b> - handle bar	155145210	<b>PAX Vacuum mattress - Ergo-Mat</b> - handles & head fixation	160875210
<b>PAX Vacuum mattress - Mummy-Mat - plus</b> - handles & head fixation	277025210	<b>PAX Vacuum mattress - Ergo-Mat</b> - handlebar & head fixation	162405210
<b>PAX Vacuum mattress - AR 1</b>	160205301	<b>PAX Vacuum mattress - Ergo-Mat</b> - handles & head fixation - Bayern	276575210
<b>PAX Vacuum mattress - AR 2</b>	155585210	<b>PAX Vacuum mattress - AR 3</b>	277095301

**Intended use of the product group:** immobilization for injuries and illnesses

According to Annex VIII, Rule 1 MDR, all devices in the product group are class 1 medical devices and the applicable essential 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 ISO 13485:2016** – Medical devices – Quality management systems – Requirements for regulatory purposes

**EN ISO 14971:2019** – Medical devices – Application of risk management to medical devices

**EN 1865-1:2010** – Patient handling equipment used in road ambulances

This EU Declaration of Conformity is valid until **25<sup>th</sup> of May 2022**

*Nils-Lasse Schneider*

Wardenburg, the 25<sup>th</sup> of May 2021

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

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

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Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN 13485:2016	Seite 1 von 1