

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.
PAX Vacuum mattress - I-Mat - handles	155165210	PAX Vacuum mattress - Ergo-Mat - handles	155135210
PAX Vacuum mattress - Mummy-Mat - handles	155155210	PAX Vacuum mattress - Ergo-Mat - handlebar	155125210
PAX Vacuum mattress - Mummy-Mat - handle bar	155145210	PAX Vacuum mattress - Ergo-Mat - handles & head fixation	160875210
PAX Vacuum mattress - Mummy-Mat - plus - handles & head fixation	277025210	PAX Vacuum mattress - Ergo-Mat - handlebar & head fixation	162405210
PAX Vacuum mattress - AR 1	160205301	PAX Vacuum mattress - Ergo-Mat - handles & head fixation - Bayern	276575210
PAX Vacuum mattress - AR 2	155585210	PAX Vacuum mattress - AR 3	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 **25th of May 2023**

Nils-Lasse Schneider

Wardenburg, the 25th of May 2022

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 ISO 13485	Seite 1 von 1