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 Stretcher Mattress – TMS – Stollenwerk	290777203	**PAX Stretcher Mattress – TMS – Stollenwerk CPS**	290787203
PAX Stretcher Mattress – TMS – Stryker M1	290797203	**PAX Stretcher Mattress – TMS – Stryker Power Pro**	290807203
PAX Stretcher Mattress – TMS – Stryker Power Pro XT	290817203	**PAX Stretcher Mattress – TMS – Ferno IN-X**	290827203
PAX Stretcher Mattress – TMS – Ferno Mondial	290837203	**PAX Stretcher Mattress – TMS – Ferno Viper**	290847203
PAX Stretcher Mattress – TMS – Kartsana BRAVA SILVER JUPITER	290857203	**PAX Stretcher Mattress – TMS – Kartsana SUPERBRAVA**	290867203
PAX Stretcher Mattress – TMS – Frestems	291443503		

Intended use of the product group: Stretcher Mattress with integrated Temperature Management System 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 ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971 – Medical devices – Application of risk management to medical devices
EN 1865-1 – Patient handling equipment used in road ambulances

This EU Declaration of Conformity is valid until **25.05.2027**

Dr. Thomas Castner

Wardenburg, 16.01.2026

Dr. med. Thomas Castner
dep. PRRC according to Art.15 MDR

Manufacturers SRN: DE-MF-000009521