

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	PAX Stretcher Mattress - TMS - Spencer QMX 777+	291707203
PAX Stretcher Mattress - TMS - Spencer QMX 779	291717203	PAX Stretcher Mattress - TMS – universal	292595201

Intended use of the product group: Stretcher Mattress for positioning the patient during treatment and transport on a main stretcher, with an integrated temperature management system to enhance patient comfort.

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 – General stretcher systems and patient handling equipment

EN 1865-2 – Patient handling equipment used in road ambulances – Power assisted stretcher

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

Wardenburg, 23.06.2026

Dr. med. Thomas Castner

Dep. PRRC according to Art.15 MDR

Manufacturers SRN: DE-MF-000009521

Version 1.1	BasDok erstellt: TC-05.04.2021	Freigabe QMB: TC-10.08.2023	Dok erstellt: ME	Freigabe VP: TC – 23.06.2026
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Firma X-CEN-TEK GmbH & Co.KG – 26203 Wardenburg			QM-System nach EN ISO 13485	Seite 1 von 1