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 Treatment Systems

Basis UDI-DI: 426074548 01625019 A6

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-Extremities-Tourniquet **P-E-T**– fluorecent yellow	138103908	**PAX-Extremities-Tourniquet** **P-E-T** – blue	138103907
PAX-Extremities-Tourniquet **P-E-T** – olive	138103921		

Intended use of the product group: Treatment of injuries and illnesses - to tie off the blood flow in cases of severe, life-threatening bleeding of the upper and lower extremities that cannot be controlled in any other way or that, depending on the situation, represent the best alternative therapy

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

This EU Declaration of Conformity is
valid until **25th of May 2022**

Nils-Lasse Schneider

Wardenburg, the 25th of May 2021

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

Manufacturers SRN: DE-MF-000009521