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EU Declaration of Conformity

(Status: 06_2025-V8)

We,

Schnitzler Rettungsprodukte GmbH & Co. KG

Rudolf-Diesel-Str.:7 - 53859 Niederkassel *Manufacturer SRN: DE-MF000005349*

declare under their sole responsibility, that the Class I medical devices listed below (non-sterile and without measuring function) according to MDR Annex VIII, Rule 1 with the intended purpose as:

Stretcher mattress accessories - Storing and securing patients on a stretcher during transport

with the basic UDI-DI: **426038867LagerungJR / 426038867KopfkissenAV / 426038867GurtsystemeNZ / 426038867Aufbewahrung9V**

comply with the relevant provisions of the EU Medical Device Regulation (EU) 2017/745 and, where applicable, other relevant Union legislation

The product group for the stretcher from manufacturer includes the following products:			
Manufacturer of stretchers: Stryker Stretcher model type: **Power Pro XT 6506 with/without XPS; Power Pro II 6507 (with XPS); M1 6100**			
Manufacturer of stretchers: Stollenwerk model type: **3002; 3003; 3006; 3008; CPS**			
Manufacturer of stretchers: Ferno model type: **Mondial; Viper**			
Manufacturer of stretchers: Kartsana model type: **Power Brava TG1000; Silver TG1100; TG1200 Silver Plus**			
Manufacturer of stretchers: Medirol model type: **Vivera-Monobloc M301; Vivera-Clinic N114-P400**			
Trade name:	**Article Nr.:**	**Trade name:**	**Article Nr.:**
Verlängerungsgurt	011-H+	Schutzabdeckung für Fahrtragen	KTA
Thermo-Visko-Kopfkissen, muldenförmig	X-006-XX	Intensivkopfkissen mit Vakuumfunktion	X-006-VI-XX
Adapter für Kopfkissen	X-06-XX	Adapter für Kopfkissen Hygiene+	X-06-H+-XX
Ablage mit Box, klappbar	X-336	Seitenpolster zur Verbreiterung der Liegefläche	X-950-XX
Unterbringungsbox	329	Tasche für Schnitzler Rollboards Zur Unterbringung in der Mitte der Trage (Stollenwerk)	331
Tasche für Schnitzler Rollboards Zur Unterbringung in der Mitte der Trage Stryker M1	332	Tasche für Schnitzler Rollboards Zur Unterbringung in der Mitte der Trage Ferno	334
Tasche für Schnitzler Rollboards	X-335		

- The conformity assessment procedure referred to in Article 19 and Annex IV has been carried out. The technical documentation is prepared in accordance with Annexes II and III. With this EU Declaration of Conformity, we, as a manufacturer of medical devices, declare that Class I, compliance without the involvement of a notified body in accordance with MDR Article 52, Paragraph(7)

- Applicable harmonized standards, national standards or other regulatory documents:
  - EN ISO 13485 – Medical devices – Quality management systems
  - EN ISO 14971 – Application of risk management to medical devices
  - EN 1865-1 – Ambulance transport equipment

- Authorized representative:
  - **[CH] Ambu-Tech AG**, Lettenstraße: 6c, 6343 Rotkreuz, Reg. Nr: CHRN-AR-20002714

Niederkassel, 30.06.2025

Lars Quadt
PRRC according to Art. 15 MDR