Schnitzler Rettungsprodukte GmbH & Co. KG
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EU Declaration of Conformity

(Stand: 11_2024-V6)

We,

Schnitzler Rettungsprodukte GmbH & Co. KG

Rudolf-Diesel-Str.:7 - 53859 Niederkassel *Manufacture 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:

Combined stretcher mattress - positioning, securing and/or immobilising patients on a stretcher during transport incl. accessories

with the basic UDI-DI: **426038867LagerungJR / 426038867GurtsystemeNZ / 426038867KopfkissenAV**
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; Silver; Super Brava**			
Manufacturer of stretchers: Medirol model type: **Vivera-Monobloc M301; Vivera-Clinic N114-P400**			
Trade name:	**Article Nr.:**	**Trade name:**	**Article Nr.:**
Kombi-Vakuum-Tragenauflage XL, ohne Baby- und Kinderrückhaltesystem	1-017MK	Kombi-Vakuum-Tragenauflage XL, mit Baby- und Kinderrückhaltesystem	1-017MK-02
Kombi-Vakuum-Tragenauflage ohne Baby- und Kinderrückhaltesystem	017 MK	Kombi-Vakuum-Tragenauflage mit Baby- und Kinderrückhaltesystem	017 MK-02
Intensiv-Kopfkissen H+ mit Headblock-Stabilität	99-006 VI	Thermo-Visko-Komfort-Kopfkissen, abklappbar	99-006 H+X
Adapter für H+-Kopfkissen, abklappbar	99-06-H+	Kombi-Vakuum-Tragenauflagen mit Tasche für RD01	017-MUT
Ersatzgurt mit 2 Schlauchgriffen und Schloss H+	99-072-H+	Transparenter Schlauchgriff Hygiene+	99-070-H+
Stirn- und Kinngurt inkl. 2 Schlauchgriffe H+	99-076-H+	Stirn- und Kinngurt H+ (ohne Griffe)	076-H+

- 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, 05.11.2024

Lars Quadt
PRRC according to Art.15 MDR