Rettungsprodukte GmbH & Co. KG
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Rettungsprodukte GmbH & Co. KG • Rudolf-Diesel-Str. 7 • 53859 Niederkassel

EU Declaration of Conformity

(status: 02_2025-V5)

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:

Vacuum Mattress for immobilization in case of injuries and illnesses and accessories

with the basic UDI-DI: **426038867Vakuummatratze2P / 426038867KopfkissenAV (accessories)**

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

The product group includes the following products and accessories			
Trade name	Article no.:	Trade name	Article no.:
Vacuum mattress, single-chamber	501 K	Vacuum mattress, multi-chamber	816 K-X
Vacuum mattress, Three-chamber	513 K	Vacuum mattress, thermo visco	816 K-TV-X
Vacuum mattress, Three-chamber	514 K	Vacuum mattress, multi-chamber	817 K-X
Vacuum mattress, single-chamber	517	Vacuum mattress, multi-chamber	818 K-X
Vacuum mattress heavy duty	527-XX-X	Vacuum mattress, multi-chamber	820 K-X
Vacuum mattress multi-chamber	813 K-X	Vacuum mattress, thermo visco	824 K-TV-X
Vacuum mattress multi-chamber	814 K-X	Vacuum mattress, multi-chamber	825 K-X
Vacuum pump (accessories)	608	Intense pillow (accessories)	006-VI
Storage bag for vacuum mattress	RD0X	Vakuummatratze ECO-LINE XL	826 K-X

- 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, 19.02.2025

Lars Quadt
PRRC according to Art.15 MDR