Schnitzler Rettungsprodukte GmbH & Co. KG
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EU Declaration of Conformity

(Stand: 08_2023-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:

Operating theatre vacuum mattress for immobilisation during surgery and with accessories

with the basic UDI-DI: 426038867Vakuummatratze2P / 426038867LagerungJR / 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 includes the following products and accessories:			
Trade name:	**Item No.:**	**Trade name:**	**Item No.:**
OP-Vakuummatratze, kurz Visz	KHOP-02-Visz	Anmodelierhilfe	KH906
OP-Vakuummatratze, kurz Gyn	KHOP-02-Gyn	Fixierungsband	KHOP99-X
OP-Vakuummatratze, lang	KHOP10	Lagerungspolster (Zubehör)	KH90X
Vakuumpumpe (Zubehör)	608	OP-Anästhesiekopfkissen für OP-Vakuummatratzen	KH00X-XX

- 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

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

Niederkassel, 08.08.2023

Lars Quadt
PRRC according to Art.15 MDR