

EU declaration of conformity

(Status: 01_2025-V6)

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:

rescue sheet - for the transport of sick or injured patient from the place of emergency to the patient stretcher/treatment table

with the basic UDI-DI: 426038867RettungstuchJ6

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

The product group includes the following products:			
Trade name:	Article no.:	Trade name	Article no.:
rescue sheet, not divisible	307-XX	rescue sheet, not divisible	310-XX
rescue sheet, divisible	301-XX	rescue sheet, divisible	X-311-XX
rescue sheet, Adiposita	304-XX	rescue sheet, Adiposita	306-XX
rescue sheet	308-XXX	rescue sheet	1-307-XX
rescue sheet	1-308-XX	Carrying sheet, hospital	309
rescue sheet	2-308	rescue sheet, with head and double foot lock	314-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
 - EN 1865-1 - Ambulance transport equipment
- Authorized representative:
 - [CH] Ambu-Tech AG, Lettenstraße: 6c, 6343 Rotkreuz, Reg. Nr: CHRN-AR-20002714
 - [GB] Johner Medical UK Limited, EDINBURGH-MIDLOTHIAN_EH39GL, MHRA Reg.NR 0000024620



Niederkassel, 30.01.2025

Lars Quadt
PRRC according to Art.15 MDR