

EU Declaration of Conformity

(Stand: 06_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 splint / dual-use splint - for immobilisation in the event of injuries and illnesses, including accessories

with the basic UDI-DI: **426038867VakuumschienenVS / 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 includes the following products and accessories			
Trade name	Article no.:	Trade name	Article no.:
Vakuum-Unterarmschiene	701-X	Vakuum-Ganzarmschiene	702-X
Vakuum-Beinschiene	703-X	Kinder-Vakuum-Armschiene	708
Kinder-Vakuum-Beinschiene	709	Einkammer-Vakuumschienen-Komplettssets	706
Mehrkommer-Vakuumschienen-Komplettssets	705-X	Kinder-Vakuumschienen-Komplettssets	707-X
Kinder-Vakuummratze und Vakuum-Armschiene	717	Mehrzweckschiene	712-XX
Aufbewahrungstasche (Zubehör)	704	Vakuumschiene- XXX-Hygiene plus	70X-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, 18.06.2025



Lars Quadt
PRRC according to Art.15 MDR