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

# EU Declaration of Conformity

(Stand: 08_2023-V3)

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:

**Patient belt system - to restrain injured or sick persons on a spineboard during transport from the emergency location to the vehicle.**

**with the basic UDI-DI: 426038867GurtsystemeNZ**

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:** | |
|---|---|
| **Trade name:** | **Item No.:** |
| Gurtspinne Hygiene+ für Spine-Board | 358-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, 08.08.2023

Lars Quadt
PRRC according to Art.15 MDR