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

EU Declaration of Conformity

(Status:03_2025-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 as:

Baby and child restraint systems, retrofittable

with the base 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 is compatible with the following strecher manufacturers:	
Manufacturer of stretchers: Stollenwerk Types: **3002; 3003; 3006; 3008; CPS**	
Manufacturer of stretchers: Ferno Model Type: **Mondial; Viper**	
Manufacturer of stretchers: Kartsana Model type: **Power Brava TG 1000; Silver TG 1100**	
Manufacturer of stretchers: **Medirol** Model type: **Vivera-Monoblock M301; Vivera Clinic N114-P400**	
Trade name:	**Product no.:**
Baby and child restraint systems	**720**

- The conformity assessment procedure referred to in Article 19 and Annex IV has been carried out. The technical documentation shall be 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 Article 52 of the MDR, 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, 05.03.2025

Lars Quadt
PRRC according to Art.15 MDR