

EU Declaration of Conformity

(Status:03_2025-V4)

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:

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 includes the following products: (for ambulance stretcher manufacturers: Stryker, Model type: Power Pro-XT 6506 with XPS / Model type: Power Pro-II 6507 with XPS / Model type: Power Pro-TL 6550 with XPS)	
Trade name:	Article No.:
Baby and child restraint systems	720 XPSNPR (stryker product code: 0058384000)
(for ambulance stretcher manufacturers: Stryker, Model type: M1 6100 Model type: Power Pro-XT 6506 without XPS / Power Pro-TL 6550 without XPS) / Power Pro-II 6507 without XPS	
Trade name:	Article No.:
Baby and child restraint systems	720 NPR (stryker product code: 0058385000)

- 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, 05.03.2025



Lars Quadt
 PRRC according to Art.15 MDR