

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



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

## EU Declaration of Conformity

(Status: 06\_2024-V0)

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 use as:

## Patient repositioning - repositioning aid for gentle repositioning of lying or bedridden persons into a carrying chair

## with the basic UDI-DI: 426038867UmlagerungAY

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

The product group for Stryker carry chair models: Stair Pro; Stair Pro-Tread-System and Ferno	
models: Fast R; EZ Glide 59THP includes the following products:	
Trade name:	Article no:
Umlagerungs-Sitz, schwarz	320

- The conformity assessment procedure in accordance with Article 19 and Annex IV has been carried out. The technical documentation has been prepared in accordance with Annexes II and III.
  With this EU Declaration of Conformity, we as a manufacturer of medical devices of the Class I, conformity without involvement of a notified body according to MDR Article 52, paragraph (7)
- Applicable harmonised standards, national standards or other regulatory documents:
  - > EN ISO 13485 Medical device quality management systems
  - > EN ISO 14971 Application of risk management to medical devices
  - > EN 1865-1 Ambulance transport equipment in ambulances
- Authorised representative:
  - > [CH] Ambu-Tech AG, Lettenstrasse: 6c, 6343 Rotkreuz, Reg. No.: CHRN-AR-20002714

Niederkassel, 26 June 2024

J. Auch

Lars Quadt PRRC according to Art.15 MDR