



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

Tel.: (0228) 971 18 97 Fax: (0228) 971 18 99

info@schnitzler-rettungsprodukte.de www.schnitzler-rettungsprodukte.de

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

EU declaration of conformity

(Stand: 08_2023-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:

Patient transfer - Transfer assistance for gently transferring patients who are lying down or bedridden

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 includes the following products:			
Trade name:	Item No.:	Trade name	Item No.:
Rollboard	RB-75-45-1/3-XXX	Rollboard	RB-85-50-1/3-XXX
Rollboard	RB-154-XX-1/3-XXX	Rollboard	RB-163-50-1/3-XXX
Rollboard	KHRB-85-50-1/2-XXX	Rollboard	KHRB-163-50-1/2-XXX

- 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

L. Quell

- > 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