

EU DECLARATION OF CONFORMITY

Name of the Manufacturer:
SRN-Nr.:

Rescue Trade OHG
DE-MF-000008980

Address:

Am Bahndamm 7
DE-63683 Ortenberg

We declare under our sole responsibility that medical products covered with this declaration of conformity are in compliance with all applicable General Safety and Performance Requirements of the Annex I MDR 2017/745

Basic UDI DI
according to

Annex VI Part C: **426072773RT-BEDSET7J**

Product name: **Disposable Bedding Set**

Purpose:

The disposable patient bedding set is intended for short-term single use in healthcare facilities, such as hospitals, ambulances, patient transport and nursing homes, and home care, and provides a physical barrier against the direct transmission of potentially infectious germs to the patient.

A disposable patient bedding set is an assortment of bedding that includes a sheet, pillow and pillowcase, and blanket and blanket cover, all typically made of one or more thin nonwoven fabrics or textile laminates.

The Risk Class of the product according to the rules described in Annex VIII is Rule 1, Risk Class I

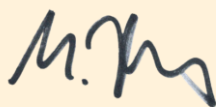
Conformity Assessment Procedure Article 52 (7) and Annex IV MDR Regulation 2017/745

Item Numbers: RTEDPP190, RTEDPP250, RTEDPP340, RTEDPP500, RTEDPP750, RTEDB190, RTEDB250, RTEDB340, RTEDB500, RTEDPWW300-L, RTEDPWB200, RTEDPWB300, RTEDPWB400, RTEDPWB500, RTEDPWB600, RTEDPWB700, RTEDW700XW, RTEDW1000XW, RTEDBWW500, RTEDBW200, RTEDBW300, RTEDBW400, RTEDBW500, RTEDBW500XXL, RTEDBW600, RTEDBW700, RTEDSE250, RTEDSE300, RTEDSE500, RTELB20, RTELB48, RTELB50, RTEVLW, RTEVLW2010, RTEVLB, RTEVLB2010, RTEVLB2110, RTEVLBXL2114, RTEVLBXL2116, RTEK, RTPPEKB, RTEK6040, RTPPEKB6040, RTEKB, RTEKBB, RTEKB6040, RTEKB6040B, RTEKB6060B, RTEKB-GB, RTEDB, RTEDPHORN

Conformity has been established by means of the above Conformity Assessment procedure and the corresponding provisions of the Regulation, using state of the art methodologies and complying with applicable standards.

The declaration is valid with the date of the signature.

Ortenberg, den 07.03.2024



(Marcus Hilka, Managing Director)