EU DECLARATION OF CONFORMITY

MANUFACTURER:

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GLN: 4262421210000

GCP: 426242121

The manufacturer declares under its own responsibility that the medical device

Product Name: ALS 328
EMDN: 3209ALS328

Intended Purpose: The carrying chair is designed for professional use and is used to transport a seated patient. At least two trained users are required for transport. Depending on local regulations, a third helper can be called in as a backup person. Additional staff may be needed for heavy patients. The indication or contraindication for using the carrying chair is the responsibility of the user and the rescue service personnel or the treating doctor. The carrying chair has no gender specificity and if the specifications of the technical data are observed, there is no limitation of the patient target group. For some patients, such as infants, pregnant or breastfeeding women, you should follow the therapy recommendations and precautions of the relevant professional societies. The carrying chair can be carried down and up stairs and rolled or carried at ground level. The carrying chair is particularly used where the space available does not allow the use of conventional stretchers. The carrying chair is equipped with two telescopic carrying handles at the front, two foldable carrying handles at the rear, a foldable footrest, two locking mushrooms and two swivel castors at the rear with parking brakes and two rigid castors equipped in front. With the carrying chair, patients can be transported in a seated position in the vehicle.

The product is tested in accordance to DIN EN 1789 and 1865 and complies with the essential requirements listed in the Regulation 2017/745 MDR directive on Medical Devices. In addition, the carrying chairs comply with EN:2007+A2:2014 Sections 5.4 and 6.3.5 - Rescue service vehicles and their equipment - Ambulances and ECE / UN Regulation No. 17, Revision 04 to the 08 series of amendments - Uniform conditions for the approval of motor vehicles with regard to the seats, anchorages and headrests. All test in accordance with EN ISO/IEC 17025:2005 or EN ISO/IEC 17020:2012 by TÜV Rheinland in 02.2019 - technical documentation no. 195XS0028-00.

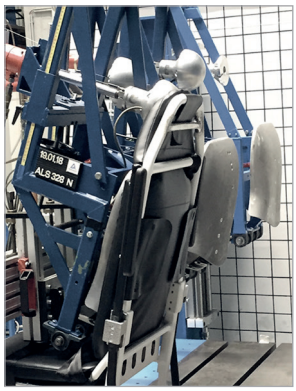
GTIN / UDI-DI: 4262421213209

GMN / Basic UDI-DI: 4262421213209ALS328JM

Device Classification: MD Class I

TESTED STANDARDS:

Quality management system - utila internal




TÜV Rheinland Group

Technischer Bericht Nr. 195XS0028-00

Prüfobjekt : Tragstuhl für Krankenkraftwagen
Typ : siehe Abschnitt 2
Auftraggeber : Utila Gerätebau GmbH & Co. KG

Dokumentation
über die Prüfung von
Haltesystemen und der Befestigung der Ausrüstung
in Rettungsdienstfahrzeugen
(Krankenkraftwagen)

Dieser Technische Bericht dient ausschließlich der Dokumentation von Prüfergebnissen und stellt kein rechtsverbindliches Prüfzeugnis im Rahmen der StVZO bzw. EG-/ECE dar.

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Troisdorf, Germany, January 2023

Sascha Ennenbach M.D.