








Product	Ally Chair AL010
---------	------------------

<b>Manufacturer</b>	<b>Staxi Corp.</b> 424 Williamson- Zebulon Rd. Williamson GA 30292 USA
<b>EU Authorized Representative</b>	<b>MedEnvoy Global B.V.</b> Prinses Margrietplantsoen 33 – Suite 123. 2595 AM The Hague. The Netherlands
<b>UK Authorized Representative</b>	<b>MedEnvoy UK Limited.</b> 85 Great Portland St, First Floor London. W1W 7LT United Kingdom

1.0 Classification and Intended Use	
<p>Staxi Ally Chair is a class I medical device under Regulation (EU) 2017/745 (for MDR). EMDN Code: V080502.</p> <p>The Staxi Transport Chair is intended to be used in the following applications: Safely transport a seated patient or passenger within healthcare or public facilities (e.g., hospitals, clinics, airports) under the control of an attendant. Typical use involves a single transport episode of transient duration (less than 1 hour). The device is intended for repeated use.</p>	 <p>Fig 1. Staxi Ally Chair</p>

2.0 Chair Part Codes – incl. Colors			
AL010-X		AL010-R	
AL010-L		AL010-C	

3.0 Instructions for safe use:
<ul style="list-style-type: none"> <li>• Before use, visually inspect the chair to confirm that all components are securely fastened, undamaged, and 4 wheels roll smoothly. Then, ensure that the brake is functioning properly by testing that the chair will not roll forward while the brake is engaged. Test that the armrest does not free-fall from the raised position</li> <li>• If any issues or potential issues are detected during inspection, do not use. Remove the chair from service and contact maintenance.</li> <li>• For the safest and most unobstructed access, entry and exit should be from the side, with the armrest in the raised position. During transport, both armrests must be lowered</li> <li>• When side entry and exit are used, the footrest may remain lowered at all times.</li> </ul>



- The footrest must be raised prior to entering the chair from the front. Once the occupant is seated and prior to disengaging the brake, the footrest must be lowered
- Before disengaging the brake or moving the chair, passenger feet must be placed firmly on the lowered footrest.
- Disengage the brake by moving the brake bar forward until it reaches the pushbar. The chair is now prepared for movement
- Engage the brake by releasing the brake bar. The chair must be stationary before the brake is engaged.
- Do not disengage brake bar while passengers enter/exit.
- Weight Capacity: 600lbs / 272kg.
- Keep the chair away from open flames and sources of intense heat.
- Passengers must be able to sit upright unassisted. Do not use this chair for young children or those without upper truncal control. Passengers must be able to hold themselves upright unassisted.
- Attendant must stay with chair when occupied.
- Do not overload the chair.
- Avoid tip-overs and falls.
  - Only one passenger at a time.
  - Avoid curbs and ledges
  - Do not attempt a U-turn or 360 maneuver on a slope, ramp or incline.
  - Do not stand on footrests.
  - Never wheel this chair on escalators or stairs.
- If a seat belt or harness is provided, it must be used and adjusted to fit the occupant
- Use caution when maneuvering the chair, to avoid pinching arms or hands between armrests and walls or door edges when navigating narrow doorways or tight gaps.
  - Avoid tight spaces.
- For transporting passengers only. Do not transport luggage in the seat or on passenger's lap.
- Never place children in car seats on this chair.

### 3.1 Accessory Instruction Information

The Following information is pertaining to Staxi Accessories fitted to the Chair.

- **Elevated Leg Rests**
  - Do not stand on the Elevated Leg Rests.
  - Elevated Leg Rests should be fully retracted when not in use.
- **Rear oxygen tank Holder**
  - Occupant should be seated prior to placing oxygen tank in holder, and oxygen tank should be removed prior to the occupant exiting the chair.
- **Seat Belt / Harness**
  - If a seat belt or harness is provided, it must be used and adjusted to fit the occupant.

### 4.0 Handling and Storage:

- Staxi chairs are designed to save space by nesting horizontally.
- Do not stack chairs on top of each other.
- Keep chairs indoors where possible, protected from weather to maximize lifespan.

**5.0 Cleaning:**

- Clean between users or when soiled using a neutral-pH, non-corrosive detergent or approved low-level disinfectant; follow the product label for dilution/contact time.
- Wipe only; do not immerse. Avoid solvents, abrasives, steam/pressure washing, and unapproved bleach.
- After cleaning, inspect critical parts; remove from service if damaged or not functioning.

**6.0 End-of-Life & Disposal Information:**

The expected lifetime of the device is 10 years. This service life is based on assessment of normal wear-and-tear under typical conditions of use and routine maintenance.

Dispose of the chair and its components in accordance with local regulations. End-of-life components may be managed through normal solid-waste or recycling streams. Cushion and textile parts may be recycled where programs exist.

**7.0 Declaration:****For Europe and United Kingdom**

Staxi Corp declares that the above-mentioned products meet the provisions of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- EN ISO 15223-1:2021 for symbols
- EN ISO 20417:2021 for labelling

**For the United States**

This device is manufactured in accordance with the applicable requirements of the U.S. Federal Food, Drug, and Cosmetic Act and 21 CFR Part 820 Quality System Regulation.

The manufacturer is registered with the U.S. Food and Drug Administration and the device is listed as required under 21 CFR Part 807.

**8.0 Notice:**

If you observe or have a serious incident with the Staxi Transport Chair, report this to Staxi and the and the competent authority of the Member State in which you are based.