# Declaration of Conformity

for the

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices**

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

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| **General Product Name:** | SitnStand |
| **Legal Manufacturer: (Name on Label)** | **Life Assistant Ltd.**<br>8 Harod St.<br>Afula 1871208<br>Israel |
| **Manufacturers SRN:** | Not Available yet |
| **Basic UDI-DI:** | 7290016780LAP100000000SU |
| **Variants:** | Refer to Appendix II – product Listing |
| **Intended Purpose:** | The SitnStand is a powered inflatable cushion intended for assisting patients suffering from mobility difficulties in rising from a seated position to standing, and in sitting down from a standing position. The SitnStand is intended to be used with chairs, wheelchairs and toilet seat, depending on its model.<br>The SitnStand is intended to be used in the home care environment while performing everyday activities, as well as in medical care facilities. |
| **MDR Classification:** | Class I, Rule 13 |
| **Notified Body:** | Class I device with no measuring function, non-sterile.<br>No notified body involved with the CE marking process |
| **EC Certificate:** | Not applicable for Class I device |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta. |
| **EU Authorised Representative SRN:** | **MT-AR-000000234** |
| **Medical Device Regulation Assessment Route:** | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. |

**Name** Gal Goldner **Position** CEO

**Signed** **Date** 13.12.2022 **Place** Afula, Israel

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

**Appendix I – Applicable Standards**

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

| Standard/CS/Document Name | Description |
|---|---|
| 2017/745 | Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices |
| EN ISO 13485:2016+A11:2021 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2019+A11:2021 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 15223-1:2021 | Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements |
| EN ISO 20417:2021 | Medical devices. Information to be supplied by the manufacturer |
| IEC 60601-1 | Medical electrical equipment, part 1: General requirements for Basic Safety and Essential Performance. |
| EN 60601 | Medical electrical equipment, part 1: General requirements for Basic Safety and Essential Performance. |
| EN 60601-1-2 | Medical Electrical Equipment- Part 1-2: General requirements for safety –Collateral standard: Electromagnetic compatibility – Requirements and tests |
| IEC 60601-1-6 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| IEC 60601-1-9 | Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design |
| IEC 60601-1-11 | Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| IEC 60086-4 | Primary Batteries – Part 4: Safety of Lithium Batteries |
| IEC 62133-2 | Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems |
| UN 38.3 testing regulation | Tests related to the transport of lithium-ion cells and batteries |
| BS 5852-1 | Fire Tests for Furniture Part 1. Methods of Test for the Ignitability by Smokers' Materials of Upholstered Composites for Seating |

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| EN 1021-1 | Fire Tests for Furniture Part 1. Methods of Test for the Ignitability by Smokers' Materials of Upholstered Composites for Seating |
| BS EN 12182 | Assistive products for persons with disability - General requirements and test methods |
| IEC 62304 | Medical device software — Software life cycle processes |
| EN ISO 14971 | Medical devices - Application of risk management to medical devices |

**Appendix II-Product Listing**

| Catalogue Number / UDI-DI | Device Name | EMDN Code |
|---|---|---|
| LAP100.000.000 | SitnStand Classic | **17976** |
| LAP200.000.000 | SitnStand for wheel chair | **17976** |
| LAP300.000.000 | SitnStand Compact | **17976** |