Certificate of Registration

In accordance with European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states.

We hereby declare that:

- **An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.**
- **The EU Authorised Representative contract has been fulfilled.**
- **Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.**

Therefore, these devices have met the requirements of the council directive and the CE mark may be applied to the products listed below.

Certificate No: CE/ISR/2018/04/11	Issue Date: 01ST September 2020	Expiry Date: 31st August 2021

Please note, due to the implementation date of the new medical device regulation (EU 2017/745) this certificate is subject to a review of the client's technical documentation before the 26th May 2021, whereupon a new Certificate of Registration is issued once compliance to the medical device regulation has been achieved.

Legal Manufacturer	EU Authorised Representative (EC REP)
Life Assistant Ltd 8 Harod St. Afula, 1871208, Israel.	Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names	MCCAA Device Registration Reference(s)
SitnStand – Mobility Assistance Device	DVC-MT-19-04-000048

Competent Authority
Malta Competition and Consumer Affairs Authority (MCCAA) Mizzi House, National Road, Blata I-Bajda, HMR 9010 Malta. Tel: +356 2395 2000 Email: info@mccaa.org.mt

This certificate is issued by:	Authorised Signature:
Advena Limited **Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013.** **Malta. Tel: +44 1926 800153 Email: info@advenamedical.com** **Registered in Malta No. C 76865**	*A. Kirby* **Anthony Kirby - Managing Director (Malta)**

This certificate is subject to the organisation maintaining their documentation in compliance with the directive stated in this certificate.

EC Declaration of Conformity

We,

Life Assistant, Ltd
8 Harod St.
Afula 1871202
Israel

Declare under our sole responsibility that the products:

- **SitnStand** - Mobility Assistance Device
  - Class I, Rule 12
  - GMDN code: 17976 (“Lifting seat cushion”)

Conform to the requirements of:
Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex V that apply to them, including all applicable Essential Requirements set out in Annex I of the Directive, and,
RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
All supporting documentation is retained at the premises of the manufacturer.

Within those requirements we have prepared the required technical documentation, put into place Corrective and Preventive Action and Vigilance procedures.

Authorized Representative in the EU:
Advena Limited
Tower Business Centre
2nd Flr, Tower Street Swatar, BKR 4013
Malta

Notified Body:
N/A – non-sterile class I device w/o measuring function

לייף אסיסטנט בע"מ
ח.פ. 514201367

Gal Goldner, CEO

07-Feb-2019
Date

This declaration shall be valid until a newer version is issued due to change in product/s or expiration of any EC certificate related to the products noted above

DoC Appendix: Intended use and applicable standards

Intended Use

The **SitnStand** is a powered inflatable cushion intended for assisting patients suffering from mobility difficulties in raising from a seated position to stand-up, and in sitting down from a stand-up position.

The SitnStand is intended to be used with chairs, wheelchairs and toilet seat, depending on its model. The SitnStand is intended to be used in home care environment as well as in medical care facilities such as old age homes

Applicable standards

Electrical Safety:

- EC/EN 60601-1: 2012, 3.1 Ed., Medical electrical equipment, part 1: General requirements for Basic Safety and Essential Performance.
- IEC/EN 60601-1-2:2014**,** Medical Electrical Equipment- Part 1-2: General requirements for safety –Collateral standard: Electromagnetic compatibility –Requirements and tests.
- IEC/EN 60601-1-6:2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- IEC 62366:2008 Medical devices -- Part 1: Application of usability engineering to medical devices
- IEC 60601-1-11:2015 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 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Assistive devices

- BS EN 12182 Assistive products for persons with disability – General requirements and test methods
- EN 1021-1 and EN 1021-2, - Furniture – Assessment of the ignitability of upholstered furniture – Part 1: Ignition source smouldering cigarette.
  - Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source match flame equivalent.

Software:

- IEC 62304:2006/AC:2008, Medical Device Software – Software Lifecycle Processes.
- IEEE 1028-1997, IEEE Standard for Software Reviews.

Risk Management:

- EN ISO 14971:2012, Implementation of Risk Management for Medical Devices.

Labeling:

- ISO 15223-1:2016, Labeling and Marking Symbols for Medical Devices
- EN 1041:2008: Information supplied by the manufacturer of medical devices

Flammability and ignitability:

- BS 5852:2006, Methods of test for assessment of the ignitability of upholstered seating by smoldering and flaming ignition sources