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/USA/2001/03/03	Issue Date: 27th January 2020	Expiry Date: * 31st January 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 2020, 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)
TiLite LLC 2701 W Court Street, Pasco, WA 99301, USA	Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names	MCCAA Device Registration Reference(s)
Manual Wheelchairs	DVC-MT-19-04-000166

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**	**Anthony Kirby – Managing Director (Malta)**

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

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MANUAL WHEELCHAIRS

Declaration of Conformity

for TiLite wheelchairs

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

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

General Product Name:	Manual Wheelchairs- See Appendix II below
Legal Manufacturer: (Name on Label)	TiLite, LLC 2701 W Court Street Pasco, WA 99301, USA
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Mobility aids for the disabled
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Brad Wolfe **Position** Regulatory Manager

Signed Brad Wolfe **Date** 23/04/2019

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.

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MANUAL WHEELCHAIRS

Appendix I – Applicable Standards

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

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
ISO 7176-1:2014	Determination of static stability
ISO 7176-3:2012	Determination of the effectiveness of brakes
ISO 7176-5:2008	Determination of overall dimensions, mass & turning space
ISO 7176-7:1998	Determination of dimensions, mass and manoeuvring pace
ISO 7176-8:2014	Requirements & test methods for static, impact & fatigue strengths
ANSI/RESNA Sections 1,3, 5, 7, 8and 15	Wheelchair Standards

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
TiLite TR	Rigid manual wheelchair - TiFit and Custom Configuration	41620
TiLite ZRA	Rigid manual wheelchair - TiFit and Custom Configuration	41620
TiLite ZR	Rigid manual wheelchair - TiFit and Custom Configuration	41620
TiLite Aero Z	Rigid manual wheelchair - Custom Configuration	41620
TiLite 2GX	Folding Manual Wheelchair with Fixed or Swing Away Footrests – Custom Configuration	41622
TiLite Aero X	Folding Manual Wheelchair with Fixed or Swing Away Footrests – Custom Configuration	41622
TiLite Aero T	Rigid manual wheelchair - Custom Configuration	41620
TiLite TRA	Rigid manual wheelchair - TiFit and Custom Configuration	41620
TiLite Twist	Rigid Manual Pediatric Wheelchair – growable (frame expands as child grows) - Fully Customizable	41620
TiLite Pilot	Rigid Manual Pediatric Wheelchair – growable (frame expands as child grows) - Fully Customizable	41620

Version History

Version	Compiled by	Date	Description
1.0	Brad Wolfe	02/21/2019	First issue
2.0	Brad Wolfe	4/16/19	Added address to legal manufacturer. Added ISO 7176-1, 3, 5, 7, 8 and ANSI/RESNA sections 1, 3, 5, 7, 8, 15 to appendix I- Applicable standards.