

# Certificate of Registration<sup>®</sup>

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: 27 <sup>th</sup> January 2020	Expiry Date: * 31 <sup>st</sup> January 2021
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*\*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 26<sup>th</sup> May 2020, whereupon a new Certificate of Registration is issued once compliance to the medical device regulation has been achieved.*

<b>Legal Manufacturer</b>	<b>EU Authorised Representative (EC REP)</b>
TiLite LLC 2701 W Court Street, Pasco, WA 99301, USA	Advena Limited, Tower Business Centre, 2 <sup>nd</sup> Flr, Tower Street, Swatar, BKR 4013 Malta.

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

<b>Competent Authority</b>
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

<b>This certificate is issued by:</b>	<b>Authorised Signature:</b>
Advena Limited Tower Business Centre, 2 <sup>nd</sup> 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.

This certificate is for the exclusive use of Advena Ltd's client and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.



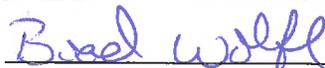
## Declaration of Conformity for TiLite wheelchairs

**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.

<b>General Product Name:</b>	Manual Wheelchairs- See Appendix II below
<b>Legal Manufacturer: (Name on Label)</b>	TiLite, LLC 2701 W Court Street Pasco, WA 99301, USA
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Intended Use:</b>	Mobility aids for the disabled
<b>MD Directive Classification:</b>	Class I
<b>Notified Body:</b>	Not Applicable for Class I
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>Medical Device Directive Assessment Route:</b>	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**  **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.



### 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, 8 and 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.