MCCAA

MALTA COMPETITION AND
CONSUMER AFFAIRS AUTHORITY

TECHNICAL REGULATIONS DIVISION

REGULATORY AFFAIRS DIRECTORATE

21st May 2018

Class I Medical Device Registration

The competent authority confirms the registration for the following medical devices for **Manufacturers Name:** Bio-Tissue, Inc. located at **Manufacturers address:** 8305 NW 27th Street, Ste 101, Doral, Florida 33122, USA with **European Authorised Representative name**: Advena Limited. located at **European Authorised Representative address**: Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta. Your registration is based upon the declaration: Manufacturers of Class I medical devices, Assemblers and Sterilisers.

Product Name/Type	Device Reference
Cliradex Wipes	DVC-MT-18-05-000010

The registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of a "medical device", and taking into account the intended purpose(s) and mode(s)of action. Kindly note that you should be operating under the Medical Devices Directive for the listed registered products, by fully complying with the essential requirements, CE marking those products and labelling them as such.

Please inform us of any changes to:

- The company information
- Additional generic groups of devices (not individual products with an existing generic group)
- Discontinuation of a generic group of devices

Kindly note that this letter does not represent any form of accreditation or approval by the Maltese Competent Authority.

Sincerely,

Ms. Ingrid Borg
Director
Regulatory Affairs Directorate
Technical Regulations Division
Malta Competition and Consumer Affairs Authority