



EU Declaration of Conformity

Object of the Declaration:

Product: Cliradex[®] Towelettes
CXC20-EU

Manufacturer: Formulated Solutions, LLC for Bio-Tissue, Inc.

Address: (Formulated Solutions) 11775 Starkey Road. Largo, FL 33773 (Bio-Tissue)
8305 NW 27th Street, Suite 101, Doral, FL 33122

This declaration is issued under the sole responsibility of Bio-Tissue, Inc.

The object of the declaration above is in conformity with the relevant Union harmonization legislation:

Annex IX of MDD 93/42/EEC Medical Devices Directive

Conformance is shown by compliance with the applicable requirements of the following documents:

Formulated Solutions (contract manufacturer of Cliradex) has implemented a QMS based on ISO13585, 21CFR820, and 21CFR210/211. Per the manufacturer's Quality Manual Rev 4, the following "latest technology and standards have been incorporated to ensure the highest quality production of formulas":

- 21 CFR Part 820
- OTC
- cGMP
- EPA
- ATF
- Bag-On Valve Aerosol Systems
- Validated USP Water System
- Product stability, methods development, evaluation and validation

Formulated Solutions also has the below registration:

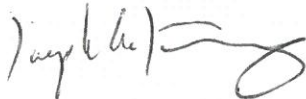
- FDA Registration pursuant to Part 207 of Title 21, US CFR (DUNS# 143266687; Labeler Code 23667; FEI# 3005779557) Certified by Registrar Corp, Hampton, VA – EXP 12/31/16
- State of Florida Department of Business & Professional Regulation Registration under provisions of Ch. 499 FS; Florida Drugs, Devices and Cosmetics (License # 06286) – EXP 04/30/17

TissueTech[™], Inc. & Subsidiaries
8305 NW 27th Street, Suite 101
Doral, Florida 33122
305.412.3430 Phone
305.412.6012 Fax



TissueTech & its Subsidiaries (Distributor of Cliradex product) has the following registration and certification:

- Bio-Tissue- Doral Distribution Site, FDA Registration (FEI#3009809074) – EXP 12/31/16
- ISO 9001:2008 Certification (N° 22071 Rev 2.) Certified by LNE GMED – EXP 09/24/17
- Company Standard Operating Procedures
- Biennial audits of manufacturer to assure compliance to TissueTech expectations and cGMPs

Signed for and on behalf of Bio-Tissue, Inc.
Place of issue: Doral, Florida, USA
Name: Joseph Jimenez
Position: Vice President, Quality and Regulatory Affairs
Signature:  29-August 2016

The technical documentation for the product is available from the above address.