

DECLARATION OF CONFORMITY

The Company

Name: Advanced Bio-Technologies Inc.
Address: ADVANCED BIO-TECHNOLOGIES, INC, 4830 WEST KENNEDY BLVD, SUITE 600,
TAMPA, FL 33609
With EU Authorised representative:

Name: Alliance Pharma S.r.l.
Address: Alliance Pharma S.r.l., Viale Restelli 5, 20124, Milan, Italy

DECLARES

Device Name: **KELO-COTE GEL**

Other Trade Names: N/A

Device Classification: I (Rule 1)

Conformity assessment procedure: Directive 93/42 EEC Annex VII

- ▶ meets the essential requirements stated in Annex I of the European Directive 93/42/EEC and its amendments Directive 2007/47 EC.
- ▶ is put on the market with the CE mark, according to the European Directive 93/42/EEC and its amendments till Directive 2007/47 EC.
- ▶ Applicable harmonised standards applied to this device:

Standard / Guideline Number	Name / Title
BS EN ISO 13485:2012	Medical Devices- Quality Management Systems – Requirements for Regulatory Purposes
BS EN ISO 14971:2012	Medical Devices- Application of Risk Management to Medical Devices
BS EN ISO 10993-1: 2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
BS EN ISO 10993-5:2009	Biological Evaluation of Medical Devices-Part 5: Tests for In-vitro cytotoxicity
BS EN ISO 10993-10:2009	Biological Evaluation of Medical Devices-Part 10: Tests for irritation and skin sensitisation
BS EN ISO 15223-1:2012	Medical Devices- Symbols to be used with Medical Device labels, labelling and information to be supplied General Requirements
BS EN 1041: 2008 + A1:2013	Information supplied by Manufacturers with Medical Devices
MEDDEV 2.7.1	Guidelines on Medical Devices; Clinical Evaluation
MEDDEV 2.12/1	Guidelines on Medical Devices; Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/2	Guidelines on Medical Devices; Post Market Clinical Follow Up Studies

The manufacturer undertakes to keep, and place at the Authorities disposal, the device technical file for a period of five years from the last date of manufacture of the product.

Date: 4/1/17


Advanced Bio-Technologies Inc.
Legal Representative