Advanced BIO-TECHNOLOGIES
SPECIALITY SKINCARE SOLUTIONS

ALLIANCE

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# EU DECLARATION OF CONFORMITY

*Legal manufacturer:* Advanced Bio-Technologies Inc.
*Address:* 4830 West Kennedy Boulevard, Suite 600, Tampa, Florida, 33609, USA

*EU Authorised Representative:* Alliance Pharma S.r.l
*Address:* Viale Restelli 5, 20124, Milan, Italy

***Declare under our sole responsibility that the product:***

*UDI DI:* N/A

*Product/trade names:* Kelo-cote Gel, Kelo-cote Scar Gel, Dervida cicatrices Gel, Youderm Clx Gel

*Product codes, catalogue numbers or other references:*

| Code | Product Name | Size / Format | Carton Quantity |
|---|---|---|---|
| KGS0.5G2D.ES,MEN | Dervida cicatrices Gel | 0.5g Sachet | 20 |
| KGS0.5G5.ES,MEN | Dervida cicatrices Gel | 0.5g Sachet | 5 |
| KCG0.5G.ES,MEN | Dervida cicatrices Gel | 0.5g Sachet | 5 |
| KG6G.ES,MEN | Dervida cicatrices Gel | 6g Tube | 1 |
| KCG15G.ES.MEN | Dervida cicatrices Gel | 15g Tube | 1 |
| KGS0.5G5.IT,MEN | Youderm Clx | 0.5g Sachet | 5 |
| KGS0.5G2D.IT.MEN | Youderm Clx | 0.5g Sachet | 20 |
| YGS0.5G.IT.MEN | Youderm Clx | 0.5g Sachet | 5 |
| KG6G.IT | Youderm Clx | 6g Tube | 1 |
| KCG15.IT | Youderm Clx | 15g Tube | 1 |
| KG15G.IT | Youderm Clx | 15g Tube | 1 |
| 513376 | Kelo-cote Gel | 15g Tube | 1 |
| 540444 | Kelo-cote Sachets | 20x0.5g | 1 |
| 593335 | Kelo-cote Gel | 6g Tube | 1 |
| 618478 | Kelo-cote Gel | 6g Tube | 1 |
| 630088 | Kelo-cote Gel | 60g Tube | 1 |
| 635191 | Kelo-cote Gel | 6g Tube | 1 |
| 641307 | Kelo-cote Gel | 15g Tube | 1 |
| 650313 | Kelo-cote Gel | 30g Tube | 1 |

*Intended use:* For the treatment and prevention of hypertrophic and keloid scars resulting from burns, general surgical procedures and trauma wounds.

*Risk Class:* I (Rule 1)

*Conformity assessment procedure:* Annex VII

*Notified Body and Certificate no.:* N/A

*Additional information:* N/A

*- is in conformity with the European Directive 93/42/EEC, as amended;*
*- meets the essential requirements stated in Annex I of the European Directive 93/42/EEC, as amended.*

| Standard | Title |
|---|---|
| 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 |
| EN ISO 10993-1: 2009 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-5:2009 | Biological Evaluation of Medical Devices-Part 5: Tests for in-vitro cytotoxicity |

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| | |
|---|---|
| ISO 10993-10:2010 | Biological Evaluation of Medical Devices-Part 10: Tests for irritation and skin sensitisation |
| EN ISO 15223-1:2016 | Medical Devices - Symbols to be used with Medical Device labels, labelling and information to be supplied General Requirements |
| EN 1041: 2008 + A1:2013 | Information supplied by Manufacturers with Medical Devices |

*Issued in Chippenham, UK, on behalf of* Advanced Bio-Technologies Inc.

*Date*: 26 November 2019

Name: Peter Butterfield

Function: CEO