

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 20512
2: Name of authorisation holder	BIO-KINETIC EUROPE LIMITED
3: Address(es) of manufacturing site(s)	BIO-KINETIC EUROPE LIMITED, 14 GREAT VICTORIA STREET, BELFAST, BT2 7BA, UNITED KINGDOM
4: Legally registered address of authorisation holder	BIO-KINETIC EUROPE LIMITED, 14 GREAT VICTORIA STREET, BELFAST, BT2 7BA, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	07/11/2016
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BIO-KINETIC EUROPE LIMITED, 14 GREAT VICTORIA STREET, BELFAST, BT2 7BA, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.2] Capsules, soft shell [1.5.1.5] Liquids for external use [1.5.1.6] Liquids for internal use [1.5.1.8] Other solid dosage forms [1.5.1.12] Suppositories [1.5.1.13] Tablets

[1.5.1.14] Transdermal patches

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products