Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)
- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation
- 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation
- 8: Authorisation Date
- 9: Annexes attached

SCOPE OF AUTHORISATION

Annex 2 Name and address of the site:

FISHER CLINICAL SERVICES UK LIMITED, LANGHURSTWOOD ROAD, HORSHAM, RH12 4QD, 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	~
[1.1] Sterile Investigational Medicinal Products	
[1.1.3] Batch certification	
[1.2] Non-sterile investigational medicinal products	
[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)	
[1.2.1.1] Capsules, hard shell	
[1.2.2] Batch certification	
[1.3] Biological investigational medicinal products	
[1.3.2] Batch certification	

UK MIA(IMP) 18693 FISHER CLINICAL SERVICES UK LIMITED

FISHER CLINICAL SERVICES UK LIMITED, LANGHURSTWOOD ROAD, HORSHAM, RH12 4QD, UNITED KINGDOM

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ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

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Annex 1 and/or Annex 2

- [1.3.2.1] Blood products
- [1.3.2.2] Immunological products
- [1.3.2.3] Cell therapy products
- [1.3.2.4] Gene therapy products
- [1.3.2.5] Biotechnology products
- [1.3.2.6] Human or animal extracted products
- [1.3.2.8] Other biological medicinal products
- IMPs

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.1] Capsules, hard shell
 - [1.5.1.2] Capsules, soft shell
 - [1.5.1.8] Other solid dosage forms
 - [1.5.1.13] Tablets
- [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
- [2.2.3] Biological medicinal products
 - [2.2.3.1] Blood products
 - [2.2.3.2] Immunological products
 - [2.2.3.3] Cell therapy products
 - [2.2.3.4] Gene therapy products
 - [2.2.3.5] Biotechnology products
 - [2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Other

Importation of QP certified IMPs from a country on the