

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 32390
2: Name of authorisation holder	THERMO ELECTRON LIMITED
3: Address(es) of manufacturing site(s)	THERMO ELECTRON LIMITED, THERMO FISHER SCIENTIFIC, FISHER BIOSERVICES DIVISION, UNIT 1, WOODSIDE, DUNMOW ROAD, BIRCHANGER, BISHOP'S STORTFORD, CM23 5RG, UNITED KINGDOM
4: Legally registered address of authorisation holder	THERMO ELECTRON LIMITED, 3RD FLOOR, 1 ASHLEY ROAD, ALTRINCHAM, WA14 2DT, 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	29/01/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

THERMO ELECTRON LIMITED, THERMO FISHER SCIENTIFIC, FISHER BIOSERVICES DIVISION, UNIT 1, WOODSIDE, DUNMOW ROAD, BIRCHANGER, BISHOP'S STORTFORD, CM23 5RG, UNITED KINGDOM

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Authorised for 'Primary labelling- not primary packaging, no open primary containers/ Importation of QP certified IMPs from a country on the 'approved country for import list'

[1.5] Packaging

[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

[2.2.3.7] Tissue Engineered Products

[2.2.3.8] Other biological medicinal products

Cell banks

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.3] Biological Active Substance

[2.3.4] Other

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