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	26/03/2026
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

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

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[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

[1.3.2.7] Tissue Engineered Products

Special Requirements

Live Cells

[1.4] Other investigational medicinal products or manufacturing activitiy

[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

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'