Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 42803
2: Name of authorisation holder	TC BIOPHARM LIMITED
3: Address(es) of manufacturing site(s)	TC BIOPHARM LIMITED - CLINICAL MANUFACTURING FACILITY, MAXIM 1, 2 PARKLANDS WAY, HOLYTOWN, MOTHERWELL, ML1 4WR, UNITED KINGDOM
4: Legally registered address of authorisation holder	TC BIOPHARM LIMITED, MAXIM 1, 2 PARKLANDS WAY, HOLYTOWN, MOTHERWELL, ML1 4WR, 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	18/03/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

TC BIOPHARM LIMITED - CLINICAL MANUFACTURING FACILITY, MAXIM 1, 2 PARKLANDS WAY, HOLYTOWN, MOTHERWELL, ML1 4WR, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

Special Requirements

Live Cells

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

Special Requirements

Live Cells

Cell Banking

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

Special Requirements

Live Cells

Cell Banking

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological