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

UK MIA 17857

PATHEON UK LIMITED

PATHEON UK LIMITED, KINGFISHER DRIVE, COVINGHAM, SWINDON, SN3 5BZ, UNITED KINGDOM

PATHEON UK LIMITED, KINGFISHER DRIVE,
COVINGHAM, SWINDON, SN3 5BZ, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

Confidential

21/11/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

PATHEON UK LIMITED, KINGFISHER DRIVE, COVINGHAM, SWINDON, SN3 5BZ, UNITED KINGDOM

Human 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 Products

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

[1.1.1.2] Lyophilisates

[1.1.1.4] Small volume liquids

[1.1.1.6] Other aseptically prepared products

Powder, Cytostatics

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.3] Small volume liquids

Issue Date: 21 Nov 2025

[1.1.2.5] Other terminally sterilised prepared products Terminally sterilised microspheres of TCA and PLGA presented in vial [1.1.3] Batch certification [1.3] Biological medicinal products [1.3.1] Biological medicinal products [1.3.1.1] Blood products [1.3.1.2] Immunological products [1.3.1.4] Gene therapy products [1.3.1.5] Biotechnology products [1.3.1.6] Human or animal extracted products [1.3.2] Batch certification [1.3.2.2] Immunological products [1.4] Other products or manufacturing activity [1.4.2] Sterilisation of active substances/excipients/finished products: [1.4.2.1] Filtration [1.4.2.3] Moist heat [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 Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products [2.1.1] Microbiological: sterility [2.1.2] Microbiological: non-sterility [2.1.3] Chemical/Physical [2.1.4] Biological [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 [2.2.3.2] Immunological products [2.2.3.4] Gene therapy products [2.2.3.5] Biotechnology products

Manufacturer's Authorisation: UK MIA 17857

Page 2 of 2

Issue Date: 21 Nov 2025

[2.2.3.6] Human or animal extracted products