Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 6180

2: Name of authorisation holder SYNERGY HEALTH STERILISATION UK LIMITED

SYNERGY HEALTH STERILISATION UK LIMITED, MORAY ROAD, ELGIN INDUSTRIAL ESTATE, SWINDON, SN2 8XS, UNITED

KINGDOM

SYNERGY HEALTH STERILISATION UK LIMITED, BRUNEL

3: Address(es) of manufacturing site(s)

CLOSE, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY,

NN11 8RB, UNITED KINGDOM

SYNERGY HEALTH STERILISATION UK LIMITED, ROYDSDALE WAY, EUROWAY INDUSTRIAL ESTATE, BRADFORD, BD4 6SE,

UNITED KINGDOM

SYNERGY HEALTH STERILISATION UK LIMITED, RENAISSANCE

HOUSE, 2200, BASING VIEW, BASINGSTOKE, RG21 4EQ, UNITED

KINGDOM

5: Scope of authorisation and dosage formsANNEX 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

4: Legally registered address of authorisation holder

Confidential

8: Authorisation Date 17/07/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SYNERGY HEALTH STERILISATION UK LIMITED, MORAY ROAD, ELGIN INDUSTRIAL ESTATE, SWINDON, SN2 8XS, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

Issue Date: 17 Jul 2025

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.5] Gamma irradiation

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SYNERGY HEALTH STERILISATION UK LIMITED, BRUNEL CLOSE, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8RB, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.5] Gamma irradiation

[1.4.2.6] Electron beam

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SYNERGY HEALTH STERILISATION UK LIMITED, ROYDSDALE WAY, EUROWAY INDUSTRIAL ESTATE, BRADFORD, BD4 6SE, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.4] Other investigational medicinal products or manufacturing activitiy

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[1.4.2.5] Gamma irradiation

Issue Date: 17 Jul 2025