Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 6180

2: Name of authorisation holder SYNERGY HEALTH STERILISATION UK LIMITED

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

UNITED KINGDOM

SYNERGY HEALTH STERILISATION UK LIMITED, MORAY ROAD,

ELGIN INDUSTRIAL ESTATE, SWINDON, SN2 8XS, UNITED

KINGDOM

SYNERGY HEALTH STERILISATION UK LIMITED, BRUNEL CLOSE, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY,

NN11 8RB, UNITED KINGDOM

SYNERGY HEALTH STERILISATION UK LIMITED, RENAISSANCE

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

KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

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 03/10/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

Issue Date: 03 Oct 2025

[1.4] Other products or manufacturing activity

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

[1.4.2.5] Gamma irradiation

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

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Annex 1

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Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.4] Other products or manufacturing activity

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

[1.4.2.5] Gamma irradiation

Manufacturer's Authorisation: UK MIA 6180

[1.4.2.6] Electron beam

Issue Date: 03 Oct 2025