

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

3: Address(es) of manufacturing site(s) SYNERGY HEALTH STERILISATION UK LIMITED , MORAY ROAD, ELGIN INDUSTRIAL ESTATE, SWINDON, SN2 8XS, UNITED KINGDOM

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

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

4: Legally registered address of authorisation holder 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 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 10/09/2024

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

[1.4] Other investigational medicinal products or manufacturing activity

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

[1.4.2.5] Gamma irradiation

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MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.4] Other investigational medicinal products or manufacturing activity [1.4.2] Sterilisation of active substances/excipients/finished products: [1.4.2.5] Gamma irradiation [1.4.2.6] Electron beam