

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

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

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

8: Authorisation Date 17/07/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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

[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 , BRUNEL CLOSE, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8RB, UNITED KINGDOM

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 [1.4.2.6] Electron beam

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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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