Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

| 1: Authorisation Number 2: Name of authorisation holder | UK MIA 6180 SYNERGY HEALTH STERILISATION UK LIMITED | |
|---|--|--|
| G | SYNERGY HEALTH STERILISATION UK LIMITED , BRUNEL CLOSE, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8RB, UNITED KINGDOM | |
| 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 , 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 | 10/09/2024 | |
| 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 , 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:

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 , MORAY ROAD, ELGIN INDUSTRIAL ESTATE, SWINDON, SN2 8XS, 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