

# 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 , BRUNEL CLOSE, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8RB, UNITED KINGDOM  SYNERGY HEALTH STERILISATION UK LIMITED, ROYDSDALE WAY, EUROWAY TRADING ESTATE, BRADFORD, BD4 6SE, UNITED KINGDOM  SYNERGY HEALTH STERILISATION UK LIMITED, RENAISSANCE HOUSE, 2200, BASING VIEW, BASINGSTOKE, RG21 4EQ, UNITED KINGDOM
4: Legally registered address of authorisation holder	
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	07/11/2022
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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b>

[ 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 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 2

Name and address of the site:

**SYNERGY HEALTH STERILISATION UK LIMITED**, ROYDSDALE WAY, EUROWAY TRADING 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 activity

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

[ 1.4.2.5 ] Gamma irradiation