

# 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b>

**[ 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

**SCOPE OF AUTHORISATION**

**Annex 2**

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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 [ 1.4.2.6 ] Electron beam