Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)
- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

- 8: Authorisation Date
- 9: Annexes attached

UK MIA 13410 STERIGENICS UK LIMITED

STERIGENICS UK LIMITED (MARKHAM VALE) , UNIT 3A, SEYMOUR LINK ROAD, WOODTHORPE, MASTIN MOOR, CHESTERFIELD, S43 3FG, UNITED KINGDOM

STERIGENICS UK LIMITED, COTES PARK ESTATE, SOMERCOTES, ALFRETON, DE55 4NJ, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

Confidential

18/12/2023 Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1 Name and address of the site:

STERIGENICS UK LIMITED (MARKHAM VALE) , UNIT 3A, SEYMOUR LINK ROAD, WOODTHORPE, MASTIN MOOR, CHESTERFIELD, S43 3FG, 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