

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

| | |
|---|--|
| 1: Authorisation Number | UK MIA 13410 |
| 2: Name of authorisation holder | STERIGENICS UK LIMITED |
| 3: Address(es) of manufacturing site(s) | STERIGENICS UK LIMITED (MARKHAM VALE) , UNIT 3A, SEYMOUR LINK ROAD, WOODTHORPE, MASTIN MOOR, CHESTERFIELD, S43 3FG, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | STERIGENICS UK LIMITED, COTES PARK ESTATE, SOMERCOTES, ALFRETON, DE55 4NJ, 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 | 18/12/2023 |
| 9: Annexes attached | 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 |