

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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|---|---|
| 1: Authorisation Number | UK MIA 13668 |
| 2: Name of authorisation holder | A.VOGEL LIMITED |
| 3: Address(es) of manufacturing site(s) | A.VOGEL LIMITED, 2 BREWSTER PLACE, IRVINE, KA11 5DD, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | A.VOGEL LIMITED, 2 BREWSTER PLACE, IRVINE, KA11 5DD, 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 | 19/11/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

A.VOGEL LIMITED, 2 BREWSTER PLACE, IRVINE, KA11 5DD, UNITED KINGDOM

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| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging [1.5.1] Primary packaging [1.5.1.2] Capsules, soft shell [1.5.1.5] Liquids for external use [1.5.1.6] Liquids for internal use [1.5.1.13] Tablets [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical |

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing