

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 10341  |
| <b>2: Name of authorisation holder</b>  | DR FALK PHARMA UK LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | DR FALK PHARMA UK LIMITED, UNIT K, BOURNE END<br>BUSINESS PARK, CORES END ROAD, BOURNE END, SL8 5AS,<br>UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | DR FALK PHARMA UK LIMITED, UNIT K, BOURNE END<br>BUSINESS PARK, CORES END ROAD, BOURNE END, SL8 5AS,<br>UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2  |
| <b>6: Legal Basis of authorisation</b>  | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations<br>2004 [SI 2004/1031]                             |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential   |
| <b>8: Authorisation Date</b>  | 21/07/2022   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**DR FALK PHARMA UK LIMITED**, UNIT K, BOURNE END BUSINESS PARK, CORES END ROAD, BOURNE END, SL8 5AS, UNITED KINGDOM

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|---|
| Human Investigational Medicinal Products  |
| Authorised Operations   |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)   |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br><b>[ 2.3 ] Other Importation Activities</b><br>[ 2.3.4 ] Other<br>Importation of QP certified IMPs from a country on the approved country for import list |

#### Any restrictions or clarifying remarks

QPs Monika Junemann and Rudolf Wilhelm are included on this licence solely for the oversight of imported IMPs following certification in an approved country in accordance with the provisions of Regulation 43(1) of UK SI 2004/1031 (as amended). Monika Junemann and Rudolf Wilhelm may not undertake QP certification of any other activities performed under this MIA(IMP).