Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 10341
2: Name of authorisation holder	DR FALK PHARMA UK LIMITED
3: Address(es) of manufacturing site(s)	DR FALK PHARMA UK LIMITED, UNIT K, BOURNE END BUSINESS PARK, CORES END ROAD, BOURNE END, SL8 5AS, UNITED KINGDOM
4: Legally registered address of authorisation holder	DR FALK PHARMA UK LIMITED, UNIT K, BOURNE END BUSINESS PARK, CORES END ROAD, BOURNE END, SL8 5AS, 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	21/07/2022
9: Annexes attached	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

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS **[2.3] Other Importation Activities** [2.3.4] Other 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).