

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 11972

2: Name of authorisation holder GILEAD SCIENCES LTD

3: Address(es) of manufacturing site(s) GILEAD SCIENCES LTD, 280 HIGH HOLBORN, LONDON, WC1V 7EE, UNITED KINGDOM

4: Legally registered address of authorisation holder GILEAD SCIENCES LTD, 280 HIGH HOLBORN, LONDON, WC1V 7EE, 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 05/06/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

GILEAD SCIENCES LTD, 280 HIGH HOLBORN, LONDON, WC1V 7EE, 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

Mr Mathijs Addink, Mr Cornelis Johan Meijer, Ms Teresa White, Ms Barbara ODwyer 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). Mr Mathijs Addink, Mr Cornelis Johan Meijer, Ms Teresa White, Ms Barbara ODwyer may not undertake QP certification of other activities performed under this MIA(IMP).