Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member

state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA(IMP) 11972 GILEAD SCIENCES LTD

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

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

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)

Regulations 2004 [SI 2004/1031]

Confidential

01/07/2024

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 and Mr Anton Jarvis 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 and Mr Anton Jarvis may not undertake QP certification of other activities performed under this MIA(IMP).

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