Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 39395

2: Name of authorisation holder VIIV HEALTHCARE TRADING SERVICES UK LIMITED

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME

OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT,

UNITED KINGDOM

4: Legally registered address of authorisation holder

OXFORD STREET, LONDON, WC1A 1DG, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

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 Confidential

authorisation

8: Authorisation Date 17/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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

6: Legal Basis of authorisation

Annex 1

Name and address of the site:

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

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