

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 16899

2: Name of authorisation holder SERVIER RESEARCH & DEVELOPMENT LIMITED

3: Address(es) of manufacturing site(s) SERVIER RESEARCH AND DEVELOPMENT LIMITED, SEFTON HOUSE, SEFTON PARK, BELLS HILL, STOKE POGES, SLOUGH, SL2 4JS, UNITED KINGDOM

4: Legally registered address of authorisation holder SERVIER RESEARCH & DEVELOPMENT LIMITED, SEFTON HOUSE, SEFTON PARK, BELLS HILL, STOKE POGES, SLOUGH, SL2 4JS, 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 02/12/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SERVIER RESEARCH AND DEVELOPMENT LIMITED, SEFTON HOUSE, SEFTON PARK, BELLS HILL, STOKE POGES, SLOUGH, SL2 4JS, 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