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

SERVIER RESEARCH AND DEVELOPMENT LIMITED, SEFTON

3: Address(es) of manufacturing site(s) HOUSE, SEFTON PARK, BELLS HILL, STOKE POGES, SLOUGH, SL2

4JS, UNITED KINGDOM

SERVIER RESEARCH & DEVELOPMENT LIMITED, SEFTON HOUSE,

4: Legally registered address of authorisation holder 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 30/09/2022

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

Issue Date: 30 Sep 2022