Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 15764

STRANDHAVEN LIMITED 2: Name of authorisation holder

STRANDHAVEN LIMITED, 641 HIGH ROAD, ILFORD, IG3 8RA,

UNITED KINGDOM

STRANDHAVEN LIMITED, UNIT 2 WELLINGTON ROAD,

LONDON COLNEY, ST. ALBANS, AL2 1EY, UNITED KINGDOM

STRANDHAVEN LIMITED, 600 HIGH ROAD, SEVEN KINGS, 4: Legally registered address of authorisation holder

ILFORD, IG3 8BS, 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)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

23/07/2024

8: Authorisation Date

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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

Annex 1

Name and address of the site:

6: Legal Basis of authorisation

STRANDHAVEN LIMITED, 641 HIGH ROAD, ILFORD, IG3 8RA, 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

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

Issue Date: 23 Jul 2024

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

STRANDHAVEN LIMITED, UNIT 2 WELLINGTON ROAD, LONDON COLNEY, ST. ALBANS, AL2 1EY, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

Page 2 of 2 Issue Date: 23 Jul 2024