

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 43870

2: Name of authorisation holder MEDLEY PHARMA LIMITED

3: Address(es) of manufacturing site(s) MEDLEY PHARMA LIMITED , UNIT 2A, OLYMPIC WAY, SEFTON BUSINESS PARK, BOOTLE, L30 1RD, UNITED KINGDOM

4: Legally registered address of authorisation holder MEDLEY PHARMA LIMITED, UNIT 2A, OLYMPIC WAY, SEFTON BUSINESS PARK, BOOTLE, L30 1RD, UNITED KINGDOM

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

6: Legal Basis of authorisation 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 authorisation Confidential

8: Authorisation Date 25/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MEDLEY PHARMA LIMITED , UNIT 2A, OLYMPIC WAY, SEFTON BUSINESS PARK, BOOTLE, L30 1RD, 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