Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)
- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

- 8: Authorisation Date
- 9: Annexes attached

UK MIA 15134 OWEN MUMFORD LIMITED

OWEN MUMFORD LIMITED, PRIMSDOWN INDUSTRIAL ESTATE, WORCESTER ROAD, CHIPPING NORTON, OX7 5XP, UNITED KINGDOM

OWEN MUMFORD LIMITED, BROOK HILL, WOODSTOCK, OX20 1TU, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

Confidential

24/09/2024

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1 Name and address of the site:

OWEN MUMFORD LIMITED, PRIMSDOWN INDUSTRIAL ESTATE, WORCESTER ROAD, CHIPPING NORTON, OX7 5XP, UNITED KINGDOM

 Human Medicinal Products

 Authorised Operations

 MANUFACTURING OPERATIONS (according to part 1)

 IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

 Part 1 - MANUFACTURING OPERATIONS

 [1.2] Non-sterile products

 [1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

 [1.2.1.17] Other non-sterile medicinal products

 Combination Adrenaline autoinjector

 [1.5.1] Primary packaging

[1.5.1.17] Other non-sterile medicinal products

The combination adrenaline autoinjector is assembled, labelled and packed by Owen Mumford. The bulk sterile prefilled syringe is supplied by the MA holder and is assembled into the combination product using in-house manufactured plastic components

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing