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 6464 WAYMADE PLC

WAYMADE PLC, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM

WAYMADE PLC, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

23/04/2024

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

WAYMADE PLC, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, 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

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

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

[1.2.1.14] Transdermal patches

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

Issue Date: 23 Apr 2024

[1.5.1.2] Capsules, soft shell
 [1.5.1.13] Tablets
 [1.5.2] Secondary packaging
[1.6] Quality control testing
 [1.6.2] Microbiological: non-sterility
 [1.6.3] Chemical/Physical
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS
[2.1] Quality control testing of imported medicinal products
 [2.1.2] Microbiological: non-sterility

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.1.3] Chemical/Physical

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation



Manufacturer's Authorisation: UK MIA 6464

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