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 44710

KINEDEXE UK LIMITED

KINEDEXE UK LIMITED, UNIT 15, MOORCROFT, HARLINGTON ROAD, UXBRIDGE, UB8 3HD, UNITED

KINGDOM

KINEDEXE UK LIMITED, UNIT 15, MOORCROFT, HARLINGTON ROAD, UXBRIDGE, UB8 3HD, UNITED

KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

01/10/2020

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KINEDEXE UK LIMITED, UNIT 15, MOORCROFT, HARLINGTON ROAD, UXBRIDGE, UB8 3HD, 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

[1.2.2] Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

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