Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 14163** KIMAL PLC 2: Name of authorisation holder

KIMAL MANUFACTURING DIVISION, UNIT 62, SHERWOOD ROAD, 3: Address(es) of manufacturing site(s)

ASTON FIELDS INDUSTRIAL ESTATE, BROMSGROVE, B60 3DR,

UNITED KINGDOM

KIMAL PLC, UNIT 10A, CLAYFIELD ROAD, WORCESTER SIX 4: Legally registered address of authorisation holder

BUSINESS PARK, WORCESTER, WR4 0AE, UNITED KINGDOM

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

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

7: Name of responsible officer of the competent authority

of the member state granting the manufacturing

authorisation

Confidential

8: Authorisation Date 03/12/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KIMAL MANUFACTURING DIVISION, UNIT 62, SHERWOOD ROAD, ASTON FIELDS INDUSTRIAL ESTATE, BROMSGROVE, B60 3DR, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.2] Secondary packaging

Issue Date: 03 Dec 2024