Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 44185 RECORDATI UK LTD 2. Name of Authorisation Holder

3. Legally registered address of

Authorisation Holder

RECORDATI UK LTD, BREAKSPEAR PARK, BREAKSPEAR WAY, HEMEL HEMPSTEAD,

HP2 4TZ, UNITED KINGDOM

RECORDATI UK LTD, BREAKSPEAR PARK, BREAKSPEAR WAY, HEMEL HEMPSTEAD 4. Address(es) of Site(s)

HP2 4TZ, UNITED KINGDOM

5. Scope of authorisation (complete for

each site under 4)

ANNEX 1

6. Legal basis of authorisation Regulation 18 of the Human Medicines Regulations 2012

7. Name of responsible officer of the competent authority of the member state granting the wholesaling

authorisation

9. Annexes attached

Confidential

8. Date 24/09/2025

> Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional)

Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which

authorisation was granted Annex 5 Additional provisions

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

RECORDATI UK LTD, BREAKSPEAR PARK, BREAKSPEAR WAY, HEMEL HEMPSTEAD, HP2 4TZ, UNITED KINGDOM

1. MEDICINAL PRODUCTS

- 1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
- 1.2 Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market
- 1.3 Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

Issue Date: 24 Sep 2025

- 2.1 Procurement
- 2.3 Supply
- 2.4 Export
- 2.6 Products imported from countries on a list
- 2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.3 Cold chain products (requiring low temperature handling)

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List

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