

# Medicines and Healthcare products Regulatory Agency

## WHOLESALE DISTRIBUTION AUTHORISATION

### (MEDICINAL PRODUCTS FOR HUMAN USE)

|                                                                                                                      |                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Authorisation Number                                                                                              | UK WDA(H) 57618                                                                                                                                                                                                                                                                                                         |
| 2. Name of Authorisation Holder                                                                                      | BIOFRONTERA UK LIMITED                                                                                                                                                                                                                                                                                                  |
| 3. Legally registered address of Authorisation Holder                                                                | BIOFRONTERA UK LIMITED, REGUS, ROTTERDAM HOUSE, 116 QUAYSIDE, NEWCASTLE UPON TYNE, NE1 3DY, UNITED KINGDOM                                                                                                                                                                                                              |
| 4. Address(es) of Site(s)                                                                                            | BIOFRONTERA UK LIMITED, REGUS, ROTTERDAM HOUSE, 116 QUAYSIDE, NEWCASTLE UPON TYNE, NE1 3DY, 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 | Confidential                                                                                                                                                                                                                                                                                                            |
| 8. Date                                                                                                              | 15/08/2025                                                                                                                                                                                                                                                                                                              |
| 9. Annexes attached                                                                                                  | 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:

**BIOFRONTERA UK LIMITED**, REGUS, ROTTERDAM HOUSE, 116 QUAYSIDE, NEWCASTLE UPON TYNE, NE1 3DY, 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)

#### 2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

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**

3.3 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