

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

- | | |
|--|---|
| 1. Authorisation Number | UK WDA(H) 46417 |
| 2. Name of Authorisation Holder | BIOCOMPOSITES LIMITED |
| 3. Legally registered address of Authorisation Holder | BIOCOMPOSITES LIMITED, MED I C 4 BUILDING, KEELE UNIVERSITY, SCIENCE PARK, KEELE, NEWCASTLE, ST5 5NL, UNITED KINGDOM |
| 4. Address(es) of Site(s) | BIOCOMPOSITES LIMITED, MED I C 4 BUILDING, KEELE UNIVERSITY, SCIENCE PARK, KEELE, NEWCASTLE, ST5 5NL, UNITED KINGDOM
BIOCOMPOSITES LIMITED, UNIT E2 TRENTHAM TRADE PARK, STANLEY MATTHEWS WAY, TRENTHAM, STOKE ON TRENT, ST4 8GA, 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 | 13/08/2025 |
| 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:

BIOCOMPOSITES LIMITED, MED I C 4 BUILDING, KEELE UNIVERSITY, SCIENCE PARK, KEELE, NEWCASTLE, ST5 5NL, 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

2.2 Holding

2.5 Other Activities

Bench top testing to characterise the effect of medicinal substances on our medical device product. Research and development of combination products - bench testing only. Manufacturing process using Sterile Water BP

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.3 Cold chain products (requiring low temperature handling)

3.4 Other Products

Medicinal products typically antibiotics or anti-fungals

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines

Name and address of the site:

BIOCOMPOSITES LIMITED, UNIT E2 TRENTAM TRADE PARK, STANLEY MATTHEWS WAY, TRENTAM, STOKE ON TRENT, ST4 8GA, 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

2.2 Holding

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines