# 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

4. Address(es) of Site(s)

KEELE, NEWCASTLE, ST5 5NL, 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 25/11/2024

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

9. Annexes attached

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

Issue Date: 25 Nov 2024

#### 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

