

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 33508

**2: Name of authorisation holder** BIOCOMPATIBLES UK LIMITED

**3: Address(es) of manufacturing site(s)** BIOCOMPATIBLES UK LIMITED, CHAPMAN HOUSE, FARNHAM BUSINESS PARK, WEYDON LANE, FARNHAM, GU9 8QL, UNITED KINGDOM

**4: Legally registered address of authorisation holder** BIOCOMPATIBLES UK LIMITED, CHAPMAN HOUSE, FARNHAM BUSINESS PARK, WEYDON LANE, FARNHAM, GU9 8QL, UNITED KINGDOM

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

**6: Legal Basis of authorisation** Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

**7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation** Confidential

**8: Authorisation Date** 14/12/2023

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**BIOCOMPATIBLES UK LIMITED**, CHAPMAN HOUSE, FARNHAM BUSINESS PARK, WEYDON LANE, FARNHAM, GU9 8QL, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms) [ 1.1.2.5 ] Other terminally sterilised prepared products Combination Product - sterile Injectable Pressurised (Aerosol) Product [ 1.1.3 ] Batch certification <b>[ 1.4 ] Other products or manufacturing activity</b> [ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.3 ] Moist heat

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical