

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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [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 [1.4] Other products or manufacturing activity [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