

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 116
<b>2: Name of authorisation holder</b>	BAXTER HEALTHCARE LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	BAXTER HEALTHCARE LIMITED, UNIT B, TAURUS BUILDING, PETERLEY ROAD, COWLEY, OXFORD, OX4 2TZ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	BAXTER HEALTHCARE LIMITED, CAXTON WAY, THETFORD, IP24 3SE, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	10/06/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**BAXTER HEALTHCARE LIMITED**, UNIT B, TAURUS BUILDING, PETERLEY ROAD, COWLEY, OXFORD, OX4 2TZ, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids [ 1.1.1.4 ] Small volume liquids [ 1.1.1.6 ] Other aseptically prepared products Cytotoxics, Monoclonal antibodies <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products

- [ 1.3.1.2 ] Immunological products
- [ 1.3.1.8 ] Other biological medicinal products
  - Non Cytotoxic & Cytotoxic-Monoclonal Antibodies
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.2 ] Immunological products
  - [ 1.3.2.8 ] Other biological medicinal products
    - Non Cytotoxic & Cytotoxic-Monoclonal Antibodies

**[ 1.5 ] Packaging**

- [ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

- [ 1.6.2 ] Microbiological: non-sterility