

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 116

2: Name of authorisation holder BAXTER HEALTHCARE LIMITED

3: Address(es) of manufacturing site(s) BAXTER HEALTHCARE LIMITED, UNIT B, TAURUS BUILDING,
PETERLEY ROAD, COWLEY, OXFORD, OX4 2TZ, UNITED
KINGDOM

4: Legally registered address of authorisation holder BAXTER HEALTHCARE LIMITED, CAXTON WAY, THETFORD,
IP24 3SE, UNITED KINGDOM

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

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials)
Regulations 2004 [SI 2004/1031]

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

8: Authorisation Date 10/06/2024

9: Annexes attached 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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [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 [1.3] Biological investigational medicinal products [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