Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK ManA 116
2: Name of authorisation holder	BAXTER HEALTHCARE LIMITED
3: Address(es) of manufacturing site(s)	BAXTER HEALTHCARE LIMITED, CAXTON WAY, THETFORD, IP24 3SE, UNITED KINGDOM
4: Legally registered address of authorisation holder	BAXTER HEALTHCARE LIMITED, CAXTON WAY, THETFORD, NORFOLK, IP24 3SE, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Regulation 5 of the current Veterinary Medicines Regulations
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	07/10/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BAXTER HEALTHCARE LIMITED, CAXTON WAY, THETFORD, IP24 3SE, UNITED KINGDOM

Veterinary Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1. MANUFACTURING OPERATIONS

[1.1] Sterile 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

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[1.1.2.3] Small volume liquids

[1.4] Other products or manufacturing activity

MHRA-GMDP MHRA-GMDP MHRA

[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

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

MHRA-GMDP MHRA-GMDP MHRA-GMDP MHRA