Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 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, IP24 3SE, 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	25/03/2024
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

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

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[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

[1.1.2.5] Other terminally sterilised prepared products

Manufacture of parametrically released products where authorised by the individual Marketing Authorisation

[1.1.3] Batch certification

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.1] Blood products

[1.3.1.6] Human or animal extracted products

[1.3.2] Batch certification

[1.3.2.6] Human or animal extracted products

[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

[1.5.1] Primary packaging

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[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

[1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.2] Terminally sterilised