

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 116
<b>2: Name of authorisation holder</b>	BAXTER HEALTHCARE LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	BAXTER HEALTHCARE LIMITED, CAXTON WAY, THETFORD, IP24 3SE, 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>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<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>	25/03/2024
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 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 <b>[ 1.3 ] Biological medicinal products</b> [ 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