

# 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,<br>THETFORD, IP24 3SE, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder                                                                  | BAXTER HEALTHCARE LIMITED, CAXTON WAY,<br>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<br>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                                                                                                  | 26/02/2026                                                                   |
| 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**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)<br>[ 1.1.2.1 ] Large volume liquids<br>[ 1.1.2.3 ] Small volume liquids<br>[ 1.1.2.5 ] Other terminally sterilised prepared products<br>Manufacture of parametrically released products where authorised by the individual Marketing Authorisation<br>[ 1.1.3 ] Batch certification<br><b>[ 1.3 ] Biological medicinal products</b><br>[ 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