# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

| | |
|---|---|
| **1: Authorisation Number** | UK MIA(IMP) 3070 |
| **2: Name of authorisation holder** | IPSEN BIOPHARM LIMITED |
| **3: Address(es) of manufacturing site(s)** | IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, UNITED KINGDOM |
| **4: Legally registered address of authorisation holder** | IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, 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** | 22/04/2026 |
| **9: Annexes attached** | Annex 1 and/or Annex 2 |

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**IPSEN BIOPHARM LIMITED**, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, UNITED KINGDOM

| Human Investigational Medicinal Products |
|---|

| Authorised Operations |
|---|
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Investigational Medicinal Products**

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.2 ] Lyophilisates

[ 1.1.1.4 ] Small volume liquids

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.5 ] Biotechnology products

**[ 1.4 ] Other investigational medicinal products or manufacturing activitiy**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 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

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of QP certified IMPs from a country on the approved country for import list

**Any restrictions or clarifying remarks**

The QPs Mrs Sandrine Weisse, Mr Adel Ouelhadj, Ms Anne-Laure Bouhier & Ms Cliana Kola are included on this licence solely for the oversight of imported IMPs following certification in an approved country in accordance with the provisions of Regulation 43(1) of UK SI 2004/1031 (as amended). Mrs Sandrine Weisse, Mr Adel Ouelhadj, Ms Anne-Laure Bouhier & Ms Cliana Kola may not undertake QP certification of other activities performed under this MIA(IMP)