

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 242

**2: Name of authorisation holder** JANSSEN-CILAG LIMITED

**3: Address(es) of manufacturing site(s)** JANSSEN-CILAG LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM

**4: Legally registered address of authorisation holder** JANSSEN-CILAG LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, 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** 28/04/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**JANSSEN-CILAG LIMITED**, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [ 2.3 ] Other Importation Activities [ 2.3.4 ] Other Importation of QP-certified IMPs from a country on the approved country for import list