

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 242
<b>2: Name of authorisation holder</b>	JANSSEN-CILAG LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	JANSSEN-CILAG LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	JANSSEN-CILAG LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<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 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 <b>[ 2.3 ] Other Importation Activities</b> [ 2.3.4 ] Other Importation of QP-certified IMPs from a country on the approved country for import list