

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 12862

**2: Name of authorisation holder** RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED

**3: Address(es) of manufacturing site(s)** RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED,  
NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,  
UNITED KINGDOM

**4: Legally registered address of authorisation holder** RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED,  
DANSOM LANE, KINGSTON-UPON-HULL, HU8 7DS, 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** 09/05/2025

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

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,  
UNITED KINGDOM**

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids [ 1.1.1.4 ] Small volume liquids <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.8 ] Other solid dosage forms

[ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Medicated Lozenges

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

[ 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