

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 49464

2: Name of authorisation holder ENTEROBIOTIX LIMITED

3: Address(es) of manufacturing site(s) ENTEROBIOTIX LIMITED, UNIT 2.3 WESTERN CAMPUS,
STARLING WAY, STRATHCLYDE BUSINESS PARK, BELLSHILL,
ML4 3PU, UNITED KINGDOM

4: Legally registered address of authorisation holder ENTEROBIOTIX LIMITED, PHOENIX HOUSE, STRATHCLYDE
BUSINESS PARK, BELLSHILL, ML4 3NJ, 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 03/12/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ENTEROBIOTIX LIMITED, UNIT 2.3 WESTERN CAMPUS, STARLING WAY, STRATHCLYDE BUSINESS PARK, BELLSHILL, ML4
3PU, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.15] Other non-sterile medicinal products Faecal Microbiota [1.2.2] Batch certification [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products

[1.3.1.6] Human or animal extracted products

[1.3.1.8] Other biological medicinal products

Faecal Microbiota

[1.3.2] Batch certification

[1.3.2.6] Human or animal extracted products

[1.3.2.8] Other biological medicinal products

Faecal Microbiota

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological