

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 16133

**2: Name of authorisation holder** ESSENTIAL NUTRITION LIMITED

**3: Address(es) of manufacturing site(s)** ESSENTIAL NUTRITION LIMITED, BANK HOUSE,  
SALTGROUNDS ROAD, BROUGH, HU15 1EG, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** ESSENTIAL NUTRITION LIMITED, BANK HOUSE,  
SALTGROUNDS ROAD, BROUGH, HU15 1EG, 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** 14/10/2021

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

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**ESSENTIAL NUTRITION LIMITED, BANK HOUSE, SALTGROUNDS ROAD, BROUGH, HU15 1EG, UNITED KINGDOM**

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.1 ] Capsules, hard shell [ 1.2.1.3 ] Chewing gums [ 1.2.1.6 ] Liquids for internal use [ 1.2.1.8 ] Other solid dosage forms [ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Semi Solid and dry extracts of funghi supercritical fluid extracts. Assembly of diagnostic kits

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.8 ] Other biological medicinal products

Enzymes, Laccase, SOD, Cytochrome, P450, Proteases derived from funghi

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

[ 1.4.1 ] Manufacture of:

[ 1.4.1.1 ] Herbal products

[ 1.4.1.2 ] Homoeopathic products

[ 1.4.1.3 ] Other

Herbal & homeopathic products, vitamins, supplements and novel foodstuffs

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.3 ] Cell therapy products

[ 2.2.3.4 ] Gene therapy products

[ 2.2.3.5 ] Biotechnology products

[ 2.2.3.8 ] Other biological medicinal products

Enzymes, Laccase, SOD, Cytochrome, P450, Proteases derived from funghi

**[ 2.3 ] Other Importation Activities**

[ 2.3.4 ] Other

Herbal & homeopathic products, vitamins, supplements and novel foodstuffs