

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA(IMP) 24822

2: Name of authorisation holder

SGS UNITED KINGDOM LIMITED

3: Address(es) of manufacturing site(s)

SGS UNITED KINGDOM LIMITED, QUAY HOUSE, UNIT 28,
PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS,
UNITED KINGDOM

4: Legally registered address of authorisation holder

SGS UNITED KINGDOM LIMITED, QUAY HOUSE, UNIT 28,
PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS,
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

09/02/2026

9: Annexes attached

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SGS UNITED KINGDOM LIMITED, QUAY HOUSE, UNIT 28, PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS,
UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[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

[1.2.1.3] Chewing gums

- [1.2.1.5] Liquids for external use
- [1.2.1.6] Liquids for internal use
- [1.2.1.8] Other solid dosage forms

Special Requirements

Powder in bottle

- [1.2.1.11] Semi-solids
- [1.2.1.12] Suppositories
- [1.2.1.13] Tablets
- [1.2.1.15] Other non-sterile medicinal products

Cytotoxic materials, steroids and sachets. Final formulation, filling, manufacture packing of biological/organic finished products for non-sterile applications.

- [1.2.2] Batch certification

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.1] Capsules, hard shell
 - [1.5.1.3] Chewing gums
 - [1.5.1.5] Liquids for external use
 - [1.5.1.6] Liquids for internal use
 - [1.5.1.8] Other solid dosage forms

Special Requirements

Powder in bottle

- [1.5.1.11] Semi-solids
- [1.5.1.12] Suppositories
- [1.5.1.13] Tablets
- [1.5.1.15] Other non-sterile medicinal products

Non-sterile medical products - Cytotoxic materials, Steroids and sachets. Final formulation, filling, manufacture, packing of biological/organic finished products for non-sterile applications.

- [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

- [2.2.2] Non-sterile products