Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 189

2: Name of authorisation holder THE MENTHOLATUM COMPANY LIMITED

THE MENTHOLATUM COMPANY LIMITED, 1 REDWOOD AVENUE,

3: Address(es) of manufacturing site(s) PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PE,

UNITED KINGDOM

THE MENTHOLATUM COMPANY LIMITED, 1 REDWOOD AVENUE,

PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PE,

UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

7: Name of responsible officer of the competent

4: Legally registered address of authorisation holder

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 01/11/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

THE MENTHOLATUM COMPANY LIMITED, 1 REDWOOD AVENUE, PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PE, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.5] Liquids for external use

[1.2.1.11] Semi-solids

[1.2.2] Batch certification

[1.5] Packaging

Issue Date: 01 Nov 2023

[1.5.1] Primary packaging

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc) Importer of stock transferred into EU warehouse

