Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 47578

NATURELLE CONSUMER PRODUCTS LIMITED 2: Name of authorisation holder

NATURELLE CONSUMER PRODUCTS LIMITED, UNIT 5 BANKMORE WAY EAST INDUSTRIAL PARK, OMAGH, BT79 3: Address(es) of manufacturing site(s)

0NZ, UNITED KINGDOM

NATURELLE CONSUMER PRODUCTS LIMITED, UNIT 5 4: Legally registered address of authorisation holder

BANKMORE WAY EAST INDUSTRIAL PARK, OMAGH, BT79

ONZ, UNITED KINGDOM

Confidential

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

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

8: Authorisation Date 20/10/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

6: Legal Basis of authorisation

Annex 2

Name and address of the site:

NATURELLE CONSUMER PRODUCTS LIMITED, UNIT 5 BANKMORE WAY EAST INDUSTRIAL PARK, OMAGH, BT79 0NZ, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.6] Other aseptically prepared products

Aseptically filled sterile sachets

[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)

Issue Date: 20 Oct 2023

[1.2.1.15] Other non-sterile medicinal products Non-sterile Sachet

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.15] Other non-sterile medicinal products Non-sterile Sachet

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

