Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 47578**

2: Name of authorisation holder NATURELLE CONSUMER PRODUCTS LIMITED

NATURELLE CONSUMER PRODUCTS LIMITED, UNIT 5 3: Address(es) of manufacturing site(s)

BANKMORE WAY EAST INDUSTRIAL PARK, OMAGH, BT79

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

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

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

2012/1916)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

20/10/2023

8: Authorisation Date

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile 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 products

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

Issue Date: 20 Oct 2023

[1.2.1.17] Other non-sterile medicinal products Non-sterile liquid and gel-filled sachets

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.17] Other non-sterile medicinal products Non-sterile liquid and gel-filled sachets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

