# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)
- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation
- 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation
- 8: Authorisation Date
- 9: Annexes attached

UK MIA 47578

NATURELLE CONSUMER PRODUCTS LIMITED

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

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

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

Confidential

20/10/2023

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)

- [ 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