# Medicines and Healthcare products Regulatory Agency

# MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 19055

2: Name of authorisation holder CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST

CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST,
3: Address(es) of manufacturing site(s)

GATE 2 ACRE MILL, SCHOOL STREET WEST, HUDDERSFIELD,

GATE 2 ACRE WILL, SCHOOL STREET WEST, HODDERSFIELD

HD3 3ET, UNITED KINGDOM

CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST,

GATE 2 ACRE MILL, SCHOOL STREET WEST, HUDDERSFIELD,

HD3 3ET, 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 authority

of the member state granting the manufacturing

4: Legally registered address of authorisation holder

authorisation

Confidential

8: Authorisation Date 25/07/2024

9: Annexes attached Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST, GATE 2 ACRE MILL, SCHOOL STREET WEST,

HUDDERSFIELD, HD3 3ET, 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

## [ 1.1 ] Sterile Products

[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[ 1.1.2.2 ] Semi-solids

[1.1.2.3] Small volume liquids

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[1.1.3] Batch certification [ 1.2 ] Non-sterile products [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use [1.2.1.8] Other solid dosage forms [1.2.1.11] Semi-solids [1.2.1.12] Suppositories [1.2.2] Batch certification [ 1.4 ] Other products or manufacturing activity [ 1.4.2 ] Sterilisation of active substances/excipients/finished products: [ 1.4.2.3 ] Moist heat [ 1.5 ] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.5] Liquids for external use [1.5.1.6] Liquids for internal use [1.5.1.8] Other solid dosage forms [ 1.5.1.11 ] Semi-solids [1.5.1.12] Suppositories [1.5.2] Secondary packaging [ 1.6 ] Quality control testing [ 1.6.1 ] Microbiological: sterility [1.6.3] Chemical/Physical Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [ 2.1 ] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.3] Chemical/Physical

## [ 2.3 ] Other Importation Activities

[2.3.1] Site of Physical Importation

Issue Date: 25 Jul 2024