

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 17854

2: Name of authorisation holder UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS FOUNDATION TRUST

3: Address(es) of manufacturing site(s) QUEENS HOSPITALS, BURTON, PHARMACY MANUFACTURING UNIT, QUEENS HOSPITAL, BELVEDERE ROAD, BURTON-ON-TRENT, DE13 0RB, UNITED KINGDOM

4: Legally registered address of authorisation holder UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS FOUNDATION TRUST, PHARMACY MANUFACTURING UNIT, QUEENS HOSPITAL, BELVEDERE ROAD, BURTON-ON-TRENT, DE13 0RB, 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 authorisation Confidential

8: Authorisation Date 13/08/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

QUEENS HOSPITALS, BURTON, PHARMACY MANUFACTURING UNIT, QUEENS HOSPITAL, BELVEDERE ROAD, BURTON-ON-TRENT, DE13 0RB, UNITED KINGDOM

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| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| 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 [1.1.2.3] Small volume liquids [1.1.3] Batch certification [1.2] Non-sterile products |

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

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.17] Other non-sterile medicinal products

Bismuth and Iodoform Paste / Impregnated Gauze

[1.2.2] Batch certification

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical