Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 50416

2: Name of authorisation holder STERLING DEESIDE LIMITED

STERLING DEESIDE LIMITED, UNIT 103, TENTH AVENUE,

3: Address(es) of manufacturing site(s)

ZONE 3, DEESIDE INDUSTRIAL ESTATE, DEESIDE, CH5 2UA,

UNITED KINGDOM

STERLING DEESIDE LIMITED, UNIT 103, TENTH AVENUE,

4: Legally registered address of authorisation holder

ZONE 3, DEESIDE INDUSTRIAL ESTATE, DEESIDE, CH5 2UA

ZUNE 3, DEESIDE INDUSTRIAL ESTATE, DEESIDE, CHS ZUA

UNITED KINGDOM

Confidential

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

6: Legal Basis of authorisation

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 21/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

STERLING DEESIDE LIMITED, UNIT 103, TENTH AVENUE, ZONE 3, DEESIDE INDUSTRIAL ESTATE, DEESIDE, CH5 2UA, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

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