

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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|---|---|
| 1: Authorisation Number | UK MIA(IMP) 59193 |
| 2: Name of authorisation holder | TOUHLIGHT DNA SERVICES LIMITED |
| 3: Address(es) of manufacturing site(s) | TOUHLIGHT DNA SERVICES LIMITED (TDS), MORELANDS BUILDING, LOWER SUNBURY ROAD, HAMPTON, TW12 2ER, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | TOUHLIGHT DNA SERVICES LIMITED, MORELANDS BUILDING, LOWER SUNBURY ROAD, HAMPTON, TW12 2ER, UNITED KINGDOM |
| 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 | Confidential |
| 8: Authorisation Date | 23/01/2025 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

TOUHLIGHT DNA SERVICES LIMITED (TDS), MORELANDS BUILDING, LOWER SUNBURY ROAD, HAMPTON, TW12 2ER, UNITED KINGDOM

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.15] Other non-sterile medicinal products Manufacture of low bioburden bulk active substance solutions in the form of small volume liquids for advanced therapy applications [1.2.2] Batch certification [1.3] Biological investigational medicinal products |

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Synthetic DNA products: Enzymatic production of customised DNA sequences in different DNA forms for use as active substances in vaccines, therapeutics and/or starting materials for ATIMP applications.

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Synthetic DNA products: Enzymatic production of customised DNA sequences in different DNA forms for use as active substances in vaccines, therapeutics and/or starting materials for ATIMP applications.

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Synthetic DNA products - Enzymatic production of customised DNA sequences in different DNA forms for use as active substances in vaccines, therapeutics and/or as starting materials for ATIMP applications.

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.15] Other non-sterile medicinal products

Primary packing of bulk small volume liquids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological