Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 59193
2: Name of authorisation holder	TOUCHLIGHT DNA SERVICES LIMITED
3: Address(es) of manufacturing site(s)	TOUCHLIGHT DNA SERVICES LIMITED (TDS), MORELANDS BUILDING, LOWER SUNBURY ROAD, HAMPTON, TW12 2ER, UNITED KINGDOM
4: Legally registered address of authorisation holder	TOUCHLIGHT 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	24/07/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

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

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[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

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

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.3] Other

Synthetic DNA products - Enzymatic prodution 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

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