

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 59193
<b>2: Name of authorisation holder</b>	TOUHLIGHT DNA SERVICES LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	TOUHLIGHT DNA SERVICES LIMITED (TDS), MORELANDS BUILDING, LOWER SUNBURY ROAD, HAMPTON, TW12 2ER, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	TOUHLIGHT DNA SERVICES LIMITED, MORELANDS BUILDING, LOWER SUNBURY ROAD, HAMPTON, TW12 2ER, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	27/02/2025
<b>9: Annexes attached</b>	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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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 <b>[ 1.3 ] Biological investigational medicinal products</b>

[ 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