Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 59193 Insp IMP 59193/36033282-0002[I]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : TOUCHLIGHT DNA SERVICES LIMITED (TDS)

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

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 59193 in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 14/08/2024 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.17] 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 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 products or manufacturing activity

[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

[1.5.1.17] 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

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.4] 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.

21/01/2025	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential