Foreign, Commonwealth & Development Office

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By: Legalisation Office (Foreign, Commonwealth & Development Office)

On: Monday 02 September 2024 10:00

Legalisation Office
United Kingdom (UK)

2 September 2024

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I, **Adewale Ademola**, solicitor of:

England and Wales

United Kingdom

Do hereby certify that the documents detailed below and attached herewith relate to the individual:

Andres Gonzalez

Signed by Adewale Ademola
08/30/2024

Signed with universign

Signature: _____

Certified to be a true copy of the original electronic / PDF document:

- Medicines and Healthcare products Regulatory Agency (MHRA) Document, Certificate Number: UK GMP 47760 Insp GMP 47760/19428771-0001[H].

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 47760 Insp GMP 47760/19428771-0001[H]

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

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : BIOLOGICAL E. LIMITED

Site address : BIOLOGICAL E. LIMITED, PLOT NO. 4, SURVEY. NO. 542/P, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL, IN-500078, INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Part 16 of The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20/11/2023, 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 Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.2] Lyophilisates

[1.1.1.4] Small volume liquids

[1.4] Other products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Restrictions or Remarks

This certification is restricted to cartridge products from line I and vial products from line III in Block 1

19/03/2024	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

MHRA-GMDP

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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Pays / Pais: United Kingdom of Great Britain and Northern Ireland

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a été signé par
ha sido firmado por
Adewale Ademola

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agissant en qualité de
quien actúa en calidad de
Solicitor

4. Bears the seal / stamp of
est revêtu du sceau / timbre de
y está revestido del sello / timbre de
Not Applicable

Certified
Attesté / Certificado

5. at
á / en
London

6. the
le / el día
02 September 2024

7. by
par / por
His Majesty's Principal Secretary of State for Foreign, Commonwealth and Development Affairs

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LONDON

10. Signature
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N. Lane

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By: Legalisation Office (Foreign, Commonwealth & Development Office)

On: Monday 02 September 2024 10:00

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