

(Convention de la Haye du 5 octobre 1961)

1. Country: United States of America

This public document

El presente documento público

2. has been signed by ha sido firmado por JACKELINE LOPEZ GONZALEZ

3. acting in the capacity of quien actúa en calidad de **Notary Public**

4. and bears the seal/stamp of y está revestido del sello/timbre de NOTARY OF PUERTO RICO

CERTIFIED

certificado

San Juan, Puerto Rico 5. at

6. on October 1, 2020

en

Secretary of State of the Government of Puerto Rico

por

7. by

8. No. 104408

bajo el número

9. Seal/Stamp Sello



Correct Certify:

Authorized Officer

10. Signature:

Firma

Raul Márquez Hernández

Secretary of State



GOBIERNO DE PUERTO RICO

Departamento de Salud Secretaría Auxiliar para Reglamentación y Acreditación de Facilidades de Salud (SARAFS)

GMP CERTIFICATE

VERÓNICA I. NÚÑEZ MARRERO, ESQ., Assistant Secretary for the Regulation and Accreditation of Health Facilities of the Department of Health (SARAFS), whose department enforces the laws of the Commonwealth of Puerto Rico, pertaining to the sale and distribution of medicinal products, certifies that:

PATHEON PUERTO RICO, INC. STATE ROAD, # 670, KM 2.7 MANATI, PR 00674 ESTABLISHMENT REGISTRATION 3003113148 LICENSE NUMBER 000240 GOOD THROUGH: JULY 14, 2022

From the documents presented by the firm to SARAFS, and which form part of the record, it is disclosed that the facility **PATHEON PUERTO RICO INC.**, is organized and operates in compliance with the standards set by the World Health Organization for Good Manufacturing Practices and Quality Control of Drugs, and that its products are registered and distributed in the United States of America and other Countries.

All pharmaceutical preparation and control facilities in the USA including those of **PATHEON PUERTO RICO, INC.**, are required by law to operate in conformance with Good Manufacturing Practice regulations for drug products. The United States Food and Drug Administration uphold this requirement through frequent inspections of such facilities.

The product manufactured at the **PATHEO PUERTO RICO**, **INC**., are registered and marketed in the USA and exported worldwide

At the request of the interested party, this certificate is issued in the City of Bayamon, Puerto Rico, and this 7 day of July, 2020.

VERÓNICA I. NÚÑEZ MARRERO, ESQ.
Assistant Secretary

ADR/Iro



Thermo Fisher Scientific
Pharma Services
Patheon, by Thermo Fisher Scientific
PO Box 31199
Manati, Puerto Rico 00674
Phone 787-621-2500
Fax 787-621-2525
www.thermofisher.com/patheon

September 24, 2020

GMP CERTIFICATION

The document attached is an exact and true copy corresponding to the GMP Certificate issued to Patheon Puerto Rico, Inc. by the Commonwealth of Puerto Rico's Health Department. The GMP Certificate is good through July 14, 2022.

Regards,

Odemaris Rosario Quality Specialist I

Affidavit Number: -1,265-

Sworn and subscribed before me by Odemaris Rosario, Quality Specialist I of Patheon Puerto Rico, Inc., of legal age, single and resident of Quebradillas, Puerto Rico, personally known to me at Manati, Puerto Rico, day 24th of September 2020.

