

APOSTILLE

(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

CARLOS A. RODRIGUEZ ORTIZ

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

5. at San Juan, Puerto Rico en

6. on February 20, 2020

a

7. by Secretary of State of the Government of Puerto Rico

por

8. No. <u>99503</u> bajo el número

9. Seal/Stamp Sello



Correct Certify:

Authorized Officer

10. Signature:

, Firma

> Elmer L. Roman Secretary of State



GOBIERNO DE PUERTO RICO

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

GMP CERTIFICATE

To be use in: CHILE

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:

MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC STATE ROAD 183, PRIDCO ZONA INDUSTRIAL PARK, LAS PIEDRAS, PUERTO RICO 00771 LICENSE NUMBER: I-000264 FACILITY ESTABLISHMENT 2650155 GOOD THROUGH: AUGUST 8, 2021

0From the documents presented by the firm to SARAFS, and which form part of the record, it is disclosed that the facility **MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC**, 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 **MSD INTERNATIONAL GMBH** (PUERTO RICO BRANCH) LLC are required by law to operate in conformance with Good Manufacturing Practice regulations for drug products. The United States Food and Drug Administration upholds this requirement through frequent inspections of such facilities.

At the request of the interested party, this certificate is issued in the City of Bayamon, Puerto Rico.

VERÓNICA I. NÚÑEZ MARRERO, ESQ. Assistant Secretary

ADR/irp

Affidavit No. 3 405

La dignidad

por principio, la libertad

Signed before me by **VERÓNICA I. NÚÑEZ MARRERO, ESQ.** Assistant Secretary for the Regulation and Accreditation of Health Facilities, known personal by me on this day of Louise 2020.

Notary Public

como meta. 1090 Marginal Ruiz Soler, Bayamón, PR 00961-7329 Tel. (787) 765-2929



ello aggra La dignidad por principio, la libertad como meta.

