

# DIÁRIO OFICIAL DA UNIÃO

*Translation of National Health Surveillance Agency - Official Gazette*

## RESOLUTION - RE NO. 2.867, AUGUST 8, 2024

THE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the use of the powers conferred on him by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board - RDC nº 585, of December 10, 2021,

Considering the fulfillment of the requirements set forth in article 39 of the Resolution of the Collegiate Board of Directors - RDC No. 497, of May 20, 2021, resolves:

Art. 1st Grant to the company(ies) listed in the ANNEX, the Certification of Good Manufacturing Practices of Active Pharmaceutical Ingredients through its automatic renewal.

Art. 2nd This Certification is valid for 02 (two) years from its publication.

Art. 3rd This Resolution comes into force on the date of its publication.

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Manufacturer: GlaxoSmithKline Biologicals S.A

Address: Parc de La Noire Epine, Rua Fleming 20, Wavre, B-1300

Country: Belgium

Manufacturer number: A.000270

Requester: Fundação Oswaldo Cruz

CNPJ: 33.781.055/0001-35

File number: 0092667/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: attenuated varicella virus; attenuated measles virus; attenuated rubella virus; attenuated mumps virus; poliovirus types 1 and 3; attenuated human rotavirus.

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# DIÁRIO OFICIAL DA UNIÃO

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## RESOLUTION - RE NO. 2.868, AUGUST 8, 2024

THE GENERAL MANAGER OF INSPECTION AND SANITARY SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred upon her by article 140, in conjunction with article 203, I, § 1 of the Internal Regulations approved by Resolution of the Collegiate Board - RDC No. 585, of December 10, 2021,

Considering compliance with the requirements of Good Manufacturing Practices recommended in current legislation, for the area of Active Pharmaceutical Ingredients, resolves to:

Art. 1st Grant to the company listed hereinafter, the Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients.

Art. 2nd This Certification is valid for 02 (two) years from its publication.

Art. 3rd This Resolution comes into force on the date of its publication.

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Manufacturer: Lonza Biologics Porriño, S.L.

Address: Calle la Relba, S/N, Porriño, 36400 Pontevedra

Country: Spain

Manufacturer number: A.000675

Requester: Astrazeneca do Brasil Ltda.

CNPJ: 60.318.797/0001-00

File number: 0089149/24-6

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Biological active pharmaceutical ingredients: Andexanet alfa.

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# DIÁRIO OFICIAL DA UNIÃO

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## RESOLUTION - RE NO. 2.869, AUGUST 8, 2024

THE GENERAL MANAGER OF INSPECTION AND SANITARY SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred upon her by article 140, in conjunction with article 203, I, § 1 of the Internal Regulations approved by Resolution of the Collegiate Board - RDC No. 585, of December 10, 2021,

Considering compliance with the requirements of Good Manufacturing Practices recommended in current legislation, for the area of Active Pharmaceutical Ingredients, resolves to:

Art. 1st Grant to the company listed hereinafter, the Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients.

Art. 2nd This Certification is valid for 02 (two) years from its publication.

Art. 3rd This Resolution comes into force on the date of its publication.

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Manufacturer: Astrazeneca AB.

Address: Forskargatan 18, 151 36 Södertälje

Country: Sweden

Manufacturer number: B.000734

File number: 0106294/24-5

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: metoprolol tartrate.

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Manufacturer: Gland Pharma Limited

Address: Plot No. 49 & 50, Jawaharlal Nehru Pharmacy, Parawada, Visakhapatnam, Andhra Pradesh - 531019 1

Country: India

Manufacturer number: B.000895

File number: 0707810/24-8

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: Tirofiban hydrochloride.

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Manufacturer: Jiangsu Weiqida Pharmaceutical Co., Ltd

Address: Nº 1 Linjiang Avenue, Linjiang Town, Haimen, Nantong, Jiangsu - 226133

Country: China

Manufacturer number: B.000131

File number: 0029834/24-4

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by semisynthesis: azithromycin dihydrate (chemical synthesis steps).

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Manufacturer: Sun Pharmaceutical Industries Ltd.

Address: Industrial Area - 3, Dewas, Madhya Pradesh 455 001

Country: India

Manufacturer number: B.000134

File number: 0136619/24-0

Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients:

Active pharmaceutical ingredient obtained by chemical synthesis: cilastatin, valacyclovir hydrochloride, imipenem, levetiracetam, orlistat, and valsartan.

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