

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Novartis Pharma AG  
Central function Basel  
Fabrikstrasse 2  
Novartis Campus  
Basel  
CH-4056  
Switzerland

Holds Certificate No:

**FS 771945**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The manufacture of Pharmaceuticals.  
Activities are related to IAF Sector 13.

For and on behalf of BSI:

David Fardel, Country Manager, Assurance - Continental Europe

Original Registration Date: 2023-07-25

Latest Revision Date: 2023-10-19

Effective Date: 2023-07-25

Expiry Date: 2026-07-24

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...making excellence a habit.™

Certificate No: **FS 771945**

Location	Registered Activities
Novartis Pharma AG Central function Basel Fabrikstrasse 2 Novartis Campus Basel CH-4056 Switzerland	The manufacture of Pharmaceuticals
Novartis Pharmaceutical Manufacturing GmbH Drug Substance Kundl Biochemiestraße 10 Kundl 6250 Austria	The manufacture of Pharmaceuticals
Novartis Pharma AG Lichtstrasse 35 Basel 4056 Switzerland	The manufacture of Pharmaceuticals
Novartis Pharma S.A.S. Centre de Biotechnologie BioProduction Operations Huningue 8, rue de l'Industrie Huningue 68330 France	Manufacturing of biological drug substances
Novartis Pharmaceutical Manufacturing LLC Business unit Mengeš Kolodvorska cesta 27 Mengeš 1234 Slovenia	Manufacturing of biological drug substances
Beijing Novartis Pharma Co., Ltd. No. 31. Yong`an Road Changping District Beijing 102200 China	Manufacturing, primary and secondary packaging, testing and release of oral solid dosage forms (tablets, hard gelatin capsules). Repacking, testing and release of imported bulk product (tablets, hard gelatin capsules). Repacking and release of imported primary packed product (soft gelatin capsules, therapeutic biologics)

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

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Location	Registered Activities
PT. Novartis Indonesia Jl. Raya TB Simatupang Rt.007/01 Kel. Gedong, Kec. Pasar Rebo Jakarta Timur Indonesia	The manufacture of Pharmaceuticals
Ciba-Geigy Japan Limited 25-1, Hioki, Tanbasayama-shi Hyogo Japan	The manufacture of Pharmaceuticals
Novartis (Bangladesh) Limited Squibb Road Cherag Ali Market Tongi I/A Gazipur 1711 Bangladesh	The manufacture of Pharmaceuticals
Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd. (BioProduction Operations Singapore) 8 Tuas Bay Lane Singapore 636986 Singapore	The manufacture of Pharmaceuticals
Novartis Pharmaceutical Manufacturing LLC Business unit Mengeš, SM Kolodvorska cesta 27 Mengeš 1234 Slovenia	The manufacture of drug substances (small molecules) and pharmaceutical intermediates
Novartis Pharma Schweizerhalle AG Rothausstrasse Pratteln 4133 Switzerland	Manufacturing of drug substances, pharmaceutical intermediates and excipients
Sandoz S.R.L. Livezeni no. 7A Targu-Mures, Jud. Mures 540472 Romania	The manufacture of Pharmaceuticals

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Information and contacts: BSI Group Italia srl, via Fara 35, Milano, Italy, phone: +39 02 6679091  
A Member of the BSI Group of Companies.

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Location	Registered Activities
Novartis Farma S.p.A. Via Provinciale Schito 131 Torre Annunziata/NA 80058 Italy	The manufacture of Pharmaceuticals
Novartis Pharma Produktions GmbH Oeflinger Str. 44 Wehr 79664 Germany	The manufacture of Pharmaceuticals
Novartis Pharma Stein AG Schaffhauserstrasse 101 Stein 4332 Switzerland	The manufacture of Pharmaceuticals
Novartis Pharmaceutical Manufacturing LLC Verovškova ulica 57 Ljubljana 1000 Slovenia	The manufacture of Pharmaceuticals
Novartis Pharma Stein AG Novartis Technical Operations Schweiz Stein Cell and Gene Therapy Schaffhauserstrasse Stein AG 4332 Switzerland	Manufacturing of cell and gene therapy products
Novartis Pharmaceuticals Corp Cell and Gene 220 E. Hanover Avenue Morris Plains New Jersey 07950 USA	The manufacture of Pharmaceuticals

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Location

Novartis Gene Therapies, Inc.  
2512 South Tri-Center Blvd.  
Durham  
North Carolina  
27713-1852  
USA

Registered Activities

Manufacturing of propriety gene therapies, drug  
substance and drug product



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