

7-5/2013/EU/WC-0283
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

21 MAY 2021

To,

M/s. Proventus Life Sciences Pvt. Ltd.,
No. C-9, Industrial Complex,
Maraimalai Nagar-603 209,
Kancheepuram District, Tamil Nadu, India

SUB:- Application for amendment of the Written Confirmation of M/s. Proventus Life Sciences Pvt. Ltd., No. C-9 Industrial Complex, Maraimalai Nagar-603 209, Kancheepuram District, Tamil Nadu, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to this office vide email dated 26.02.2021 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended certificate. The condition of the Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India will remain same.

Please acknowledge the receipt.

Yours faithfully,



(Dr. V. G. Somani)
Drugs Controller General (India)


20/05/2021



GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

(Amended)
Annexure-1
CERTIFICATE NO. : WC-0283

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Name and address of site: M/s. Proventus Life Sciences Pvt. Ltd.,
No. C-9, Industrial Complex,
Maraimalai Nagar-603 209,
Kancheepuram District, Tamil Nadu, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Primidone BP/Ph.Eur	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 02nd Nov 2023

Signature

[Handwritten Signature]
20/05/2021

Stamp of the authority and date



21 MAY 2021