File No.: COS/PostAppr/2019/7633

Central Drugs Standard Control Organisation (HQ)
Directorate General of Health Services
Ministry of Health and Family Welfare
(Cosmetics Division)

FDA Bhawan, Kotla Road New Delhi-110002

Dated:-29-May-2020

To,

M/s Pm International India Pvt Ltd, 6th Floor, Suite No. 10 and 11, Apeejay Business Centre, Arunachal Building, Barakhamba Road New Delhi, Central Delhi, Delhi (India) - 110001

Sub:- Registration Certificate in Form 43 (R.C. No. RC/COS-001240) under Drugs and Cosmetics Rules for the purpose of import of cosmeticsmanufactured by M/s. PM International AG, 15, Waistrooss, L-5445, Schengen - (Luxembourg) Telephone No.: 3523396671 FAX: 3523396671 E-Mail: contact-india@pm-international.com Reg.

Sir.

Registration Certificate in Form 43 under the Drugs and Cosmetics Rules is herewith forwarded for the import of Cosmetics into India. Subject to the following conditions:-

- 1. The Registration Certificate shall be produced by the Authorized Importer/Distributor/Agents as and when required by the Licensing Authority/Regulatory Authority.
- 2. Dispute, if any, in respect of the payment of fees and submission of TR6 challan, shall be settled between the bank and applicant.
- 3. The Cosmetics will be required to be withdrawn from sale in the events of non compliance of Standards.
- 4. Each consignment of the Cosmetics to be imported by you shall be accompanied by a test analysis reports.
- 5. This Registration Certificate, unless it is sooner suspended or cancelled, shall be valid for a period of three years.
- 6. No cosmetics shall be imported unless it complies with the specifications prescribed under Schedule S and Schedule Q or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case the cosmetics is not included under Schedule S, it shall meet with specification under the rules and standards applicable to it in the country of origin.
- 7. The use of the term category in the Registration Certificate instead of brands are in line with the guidelines and also subjected to the amendments of the rules to be made in due course of time.

Please note that Registration Certificate issued is liable to be suspended/ cancelled, if any of the conditions stipulated above is not compiled with, apart from any other conditions that may be taken under the provision of the Drugs & Cosmetics Act, 1940 and the Rules thereunder.

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Please acknowledge the receipt.

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Copy To: All Zonal, Sub-Zonal and Port Offices of CDSCO.



F. No.: COS/PostAppr/2019/7633



# **GOVERNMENT OF INDIA**

# Central Drugs Standard Control Organisation Ministry of Health & Family Welfare FDA BHAWAN, KOTLA ROAD, NEW DELHI - 110 002 (INDIA)

Form 43

(See rule 129-C)

### **REGISTRATION CERTIFICATE**

Registration Certificate issued for import of cosmetics into India Under Drugs and Cosmetics Rules, 1945

## Registration Certificate No. RC/COS-001240

Date:29-May-2020

1.M/s. PM International AG, 15, Waistrooss, L-5445, Schengen - (Luxembourg) Telephone No.: 3523396671 FAX: 3523396671 E-Mail: contact-india@pm-international.com having factory premises at (List enclosed as Annex-I) has been registered under rule 129-C as a manufacturer and is hereby issued this Registration Certificate.

2. Name(s) of cosmetics, along with their brand names and pack sizes and variants which may be imported under this Registration Certificate:

#### List enclosed as Annex-I

- **3.** This Registration Certificate shall be in force from **13-May-2020** to **12-May-2023** unless it is sooner suspended or cancelled under the rules.
- 4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent or importer in India or by the manufacturer, namely M/s Pm International India Pvt Ltd, 6th Floor, Suite No. 10 and 11, Apeejay Business Centre, Arunachal Building, Barakhamba Road New Delhi, Central Delhi, Delhi (India) 110001 who shall be responsible for the business activities of the manufacturer, in India in all respects.
- **5.** This Registration Certificate is subject to the conditions, stated overleaf and to such other conditions as may be specified in the Drugs and Cosmetics Act, 1940 and the Rules made thereunder, from time to time in this regard.



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Place: New Delhi

Date:29-May-2020

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#### **Conditions of the Registration Certificate**

- 1. The Registration Certificate shall be produced by the authorised importer/distributor/agent as and when required by the Licensing Authority/Regulatory Authority.
- 2. The manufacturer or his authorised importer/distributor/agent in India shall inform the licensing authority forthwith in the event of any administrative action taken namely, market withdrawal,regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any cosmetic pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the cosmetic is marketed/sold or distributed.

The dispatch and marketing of the cosmetic in such cases shall be stopped and the Licensing Authority shall be informed immediately. Further action in respect of such stopped marketing of cosmetic shall be followed as per the direction of Licensing Authority. In such cases, action equivalent to that taken with reference to the concerned cosmetic in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the cosmetic from Indian market within 48 hours time period.

- 3. The manufacturer or his authorised agent/importer/distributor or subsidiary in India shall inform the licensing authority within 30 days, in writing, in the event of additional variant/additional cosmetic category/additional manufacturing location or any change in labelling or in testing, or in documentation of any of the cosmetic pertaining to this Registration Certificate. In such cases, where there shall be any additional variant/additional cosmetic category/additional manufacturing location, as the case may be, at the discretion of the Licensing Authority, the manufacturer or his authorised agent/importer/distributor/ subsidiary in India shall apply for necessary approval within 30 days by submitting a separate application along with the registration fee.
- 4. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing, in the event, of any change in the constitution of the firm and/or address of the registered office/ factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless,in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises.

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## F. No.: COS/PostAppr/2019/7633

## List of Cosmetics permitted to import under Registration Certificate No. RC/COS-001240 dated 13-May-2020 valid up to 12-May-2023

1	Product Category : Face care products other than face mask	Cosmetic Name along with their brand name: FitLine Skin - Anti-aging Ultimate young Product Variant: Nil Pack Size(s): 15ml, 0.5 FL .OZ/50ml Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Graf-
2	Product Category : Face care products other than face mask	von-Zeppelin-Str.2-4, D 56410, Montabaur-Germany  Cosmetic Name along with their brand name: FitLine Skin - Anti-aging 4ever Product Variant: Nil  Pack Size(s): 15ml, 0.5 FL .OZ/ 50ml,1.7 FL OZ  Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany
3	Product Category : Face care products other than face mask	Cosmetic Name along with their brand name: FitLine Skin - Anti-aging Brightening 4ever Product Variant: Nil Pack Size(s): 15ml, 0.5 FL .OZ/ 50ml,1.7 FL OZ Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany
4	Product Category : Face care products other than face mask	Cosmetic Name along with their brand name: FitLine Skin - Cleansing Tonic Product Variant: Nil Pack Size(s): 200ml Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany
5	Product Category : Face care products other than face mask	Cosmetic Name along with their brand name: FitLine Med - Q10 Oxy Repair Face Product Variant: Nil Pack Size(s): 50ml Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany
6	Product Category : Body care products	Cosmetic Name along with their brand name: FitLine Skin - Cleansing Cleansing Lotion Product Variant: Nil Pack Size(s): 200ml Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany
7	Product Category : Body care products	Cosmetic Name along with their brand name: FitLine Med - Q10 Oxy Repair Body Product Variant: Nil Pack Size(s): 150ml Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany
8	Product Category : Body care products	Cosmetic Name along with their brand name: FitLine Med - Active Gel Product Variant: Nil Pack Size(s): 150ml Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany
9	Product Category : Body care products	Cosmetic Name along with their brand name: FitLine Med - Clear skin Product Variant: Nil Pack Size(s): 30ml Actual Manufacturing Premise(s): 1) Bio-Gen Milchserum Marketing GmbH, Grafvon-Zeppelin-Str.2-4, D 56410, Montabaur-Germany

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Page No.: 3

Date:29-May-2020

Place: New Delhi



## F. No.: COS/PostAppr/2019/7633

List of Cosmetics permitted to import under Registration Certificate No. RC/COS-001240 dated 13-May-2020 valid up to 12-May-2023

TOTAL TWO (2) CATEGORIES WITH NINE (9) PRODUCTS ONLY.



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Page No.: 4

Date:29-May-2020

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