By the Distributor of Dermaceutic in Switzerland: Pure Suisse Laboratoire SA Rue de St Jean 19A 1203 Genève

URGENT SAFETY NOTICE

Mandatory Product Recall – 27th of June 2019

Products Concerned: Cosmo Peel 12, 15, 18, 20

References: Cosmo Peel Kit 12% - COS12%-KIT – all kits

Cosmo Peel Kit 15% - COS15%-KIT – all kits Cosmo Peel Kit 18% - COS18%-KIT – all kits Cosmo Peel Kit 20% - COS20%-KIT – all kits

Variants: The 'TESTER UNIT' and sample sachets (non-sellable) are also concerned

Lot Number: All lots

Action: Mandatory Product Recall

Manufacturer: Legal Address:

Dermosciences France Sarl, 60 rue Yves Klein, 06480 La Colle sur Loup, France

Office / Laboratoire Address:

Dermosciences France Sarl, 15 chemin des Presses, 06800 Cagnes-sur-mer, France

Responsible Person: Nicola Fagiuoli, Founder of Dermosciences France

Madam, Sir,

During the transposing of the 'Cosmo Peel Cream' to a new contract manufacturer, the R&D team of Dermosciences France discovered (1.) the non-conformity of the packaging of Cosmo Peel Cream, which declares ingredients that are not contained in the formula, (2.) the presence of non-declared medicinal ingredients / poisons: hydrocortisone and retinoic acid. These discoveries are the subject of an investigation in France. Pure Suisse Laboratoire SA, the distributor of Dermaceutic in Switzerland, also learned that (3.) the contract manufacturer of both the TCA and the Cosmo Peel Cream does not have any accreditation for manufacturing, neither of cosmetics nor of medical devices.

Pure Suisse Laboratoire SA also found out that those responsible for these 'non-conformities' have been running this since the launch of these products – more than 10 years ago.

Pure Suisse Laboratoire SA would like to apologize for these non-conformities, which were entirely outside of our control until now. Due to the nature of these findings, the nature of the risks and the severe contra-indications of these non-declared medicinal substances, Pure Suisse Laboratoire SA requests a recall of Cosmo Peel: the TCAs and the Cosmo Peel Cream.

We request that you immediately stop all use of these products.

Measure to be taken immediately by the client

Based on our files, you have ordered these products. Please identify their location and put them into quarantine.

<u>Please confirm by signing the attached form to acknowledge that you have been notified, have undertaken the required measures and that you will return non-conforming, drug-filled products.</u>

A credit or replacement product will be offered in compensation of the returned products in fall 2019. Please contact <u>orders@puresuisse.com</u> if you have any questions.

By the Exclusive Distributor of Dermaceutic in Switzerland: Pure Suisse Laboratoire SA Rue de St Jean 19A 1203 Genève

Address:

Zip Code / City:

Document filled out by:

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This report was prepared in line with the norm EN 13485.

Telephone #:

Email: