

# DERMOSCIENCES

## SECURITY NOTIFICATION

### Medical Devices

Dispatch n°2

Reference : **BR-2019-02** - Type : **Update**

Date: 16/01/2020

<b>Recipient</b>	For all the distributors of Dermosciences Ltd and all their customers
<b>Device type</b>	Peel solution included in Cosmo Peel TCA kits
<b>Products concerned</b>	Medical Device Class I – Brand Dermaceutic Laboratoire  <b>Batches manufactured in December 2017:</b> <ul style="list-style-type: none"><li>• TCA 12 batch 17L001 (affected kits batches: BJ001 / CA003)</li><li>• TCA 15 batch 17L002 (affected kits batches: BJ003 / CA001)</li><li>• TCA 18 batch 17L003 (affected kit batches: BJ002 / BL002 / BL003)</li><li>• TCA 20 batch 17L004 (affected kit batches: CA002 / CA002-1 / CD001 / CD001-1)</li></ul>
<b>Primary clinical purpose of device</b>	The device is used by doctors in an in-clinic protocol of peeling to treat the appearance of wrinkles, texture irregularities, smoker's complexion and pigment disorders.
<b>Manufacturer, representative and address</b>	Dermosciences France, Nicola Fagioli, 15 Chemin des Presses, 06800 Cagnes sur Mer, France

### Description

#### Update:

The FSN of the 08/01/2020 was updated as follow:

- **Addition of TCA 12 in the concerned products list**
- **Rectification of the concerned batch numbers (17L00X replaced by 17L00X)**
- **Update of the corrective action to be implemented**

DERMOSCIENCES France is implementing a voluntary corrective action on the medical devices (hereinafter MD) TCA 12, TCA 15, TCA 18 and TCA 20 (batches 17L001, 17L002, 17L003 and 17L004).

DERMOSCIENCES France noticed that the expiry date was not printed on the MD TCA 12, TCA 15, TCA 18 and TCA 20 primary glass bottles **manufactured in December 2017**. The expiry date was only printed and visible on the secondary packaging of those MDs.

### Risk analysis

The level of incidence is considered as critical: there is a potential risk of use beyond the expiry date.

Dermosciences France estimates that the impacted medical devices are no longer available on the market due to the number of units circulated and the overall high stock rotation.

As a precautionary measure and to confirm the initial estimation, Dermosciences France wishes to set up the corrective actions listed below.

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## What we would like you to do

- MDs not yet sold: fill and send us the **Annex 1**. Place the products into quarantine. Wait for further instructions.
- MDs already sold: contact your customers to ensure products will be used before the expiry date and share this security notification with **Annex 3**. Suggested answer form: **Annex 2**.

**Please note that a reply is required by 24/01/2020.**

## Additional information

Please report all device-related incidents to Dermosciences France.

If you have any additional questions, we are available by telephone at your account manager's usual number, by email at [quality@dermaceutic.com](mailto:quality@dermaceutic.com) or by post at:

*Dermosciences France, 15 Chemin des Presses, 06800, Cagnes-sur-Mer.  
Service Qualité et Affaires réglementaires.*

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## ANNEX 1: DISTRIBUTOR ANSWER FORM

(must be filled in by distributor)

Reference: BR-2019-02 – Date: 16/01/2020

Security notification related to a report on a default on the TCA 12, TCA 15, TCA 18 and TCA 20

We kindly ask you to complete the below form and send it to us at [quality@dermaceutic.com](mailto:quality@dermaceutic.com).

**I hereby certify that:**

- I have received the Security Notification of DERMOSCIENCES France
- I shared informed the impacted professional users of this security notification

Distributors/Importers (Tick all that apply)	
<input type="checkbox"/>	I have checked my stock and quarantined inventory
<input type="checkbox"/>	I have identified customers that received or may have received this device
<input type="checkbox"/>	I have received replies from all identified customers
<input type="checkbox"/>	Neither I nor any of my customers have the affected devices

Please fill the following table if you still hold the affected MDs (use an excel sheet if insufficient space):

MD name	Batch number	Quantity

**DEADLINE to return the form: 24/01/2020**

Distributor: .....

Date: .....

Signature: .....

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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## ANNEX 2: PROFESSIONAL USER ANSWER FORM

(must be filled in by professional customers)

Reference : BR-2019-02 – Date: 16/01/2020

Security notification related to a report on a default on the TCA 12, TCA 15, TCA 18 and TCA 20

We kindly ask you to complete the below form and send it to *(to be completed)*.

**I hereby certify that I have received the Security Notification**

- I no longer hold stock of this product in my premises
  
- I hold the following batches and quantities and confirm that the products will be used before the expiry date as mentioned in annex 3:

MD name	Batch number	Quantity

Entity: .....

Contact name: .....

Address: .....

Date: .....

Signature: .....

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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## ANNEX 3: LIST OF MDs WITH THEIR EXPIRY DATES

Reference : BR-2019-02 – Date: 16/01/2020

MD name	Batch Number	Expiry date	Included in the kit:	Batch number of the kit:
<b>TCA 12</b>	17L001	<b>12/2021</b>	Cosmo Peel 12%	BJ001 CA003
<b>TCA 15</b>	17L002	<b>12/2021</b>	Cosmo Peel 15%	BJ003 CA001
<b>TCA 18</b>	17L003	<b>12/2021</b>	Cosmo Peel 18%	BJ002 BL002 BL003
<b>TCA 20</b>	17L004	<b>12/2021</b>	Cosmo Peel 20%	CA002 CA002-1 CD001 CD001-1