DERMOSCIENCES

SECURITY NOTIFICATION

Medical Devices

Dispatch n°1

Reference : **BR-2019-03 -** Type : **New**

Date: 16/01/2020

Recipient	For all the distributors and all their customers
Device type	Peel solution and post-Peel cream
Products concerned	• Mela Peel kits batches **L01 & L02** ***Containing Mela Peel batch L01 and Activa Peel batches L02 & L03*** • Mela Peel Forte kits batches **BI001 & FA001** ***Containing Mela Peel Forte batch M01 and Activa Peel Forte batch L02***
Primary clinical purpose of device	Devices are used by doctors in an in-clinic protocol of peeling.
Manufacturer, representative and address	Dermosciences France, Nicola Fagiuoli 15 Chemin des Presses, 06800 Cagnes sur Mer, France

Description & analysis

DERMOSCIENCES France is implementing a voluntary corrective action on medical devices (MD). DERMOSCIENCES France noticed that the expiry date was not printed on the above-mentioned MD primary packaging. An expiry date was only printed on the secondary packaging.

All the above-mentioned kits are now expired or about to expire.

Dermosciences France wishes to inform the users of the expiry date and ensure the products will no longer be used after the expiry date.

What we would like you to do

- MDs not yet sold: fill and send us the **Annex 1.** Place the products into quarantine. A reply is requested by 24/01/2020;
- MDs already sold: contact your customers to verify if they still hold the products. Share with them this security notification with **Annex 3**. Send us a summary of the answers provided by your customers (suggested answer form: **Annex 2**). Recall the products and place them into quarantine. A reply is requested by 24/01/2020
- For all MDs placed into quarantine: send us an evidence of the collected products, proceed with the destruction of the MDs and send us a destruction note.

Please note that a reply is required within 2 weeks.

Additional information

If you have any additional questions, we are available by telephone at your account manager's usual number or by email at quality@dermaceutic.com.

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ANNEX 1: DISTRIBUTOR ANSWER FORM

(must be filled in by distributor)

Reference: BR-2019-03 – Date: 16/01/2020

We kindly ask you to complete the below form and send it to us at quality@dermaceutic.com.

I hereby certify that:

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

Tick all that apply	
☐	I have checked my stock and quarantined inventory
☐	I have identified customers that received or may have received this device
☐	I have received replies from all identified users and I have ensure products will not be used beyond the expiry date
☐	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

☐	I have destroyed the above list of medical devices

Quantity destroyed:
Date of destruction:

Distributor Name:

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-2019-03 – Date: 16/01/2020

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 still hold the following products and confirm they will be returned:

MD name	Batch number	Quantity

Entity:

Contact name:

Address:

Date:

Signature:

Please send back to the following address (*to be completed*):

_____

Join this Annex form to the goods shipped.

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-2019-03 – Date: 16/01/2020

Kit name:	Kit batch number:	MD name:	MD batch Number:	Expiry date:
Mela Peel Kit	L01 L02	**Activa Peel**	L02 L03	**02/2019** **03/2019**
		Mela Peel	L01	**03/2019**
Mela Peel Forte Kit	BI001 FA001	**Activa Peel Forte**	L02	**10/2020**
		Mela Peel Forte	M01	**03/2020**