DERMOSCIENCES

SECURITY NOTIFICATION

Medical Devices

Dispatch n°1 Reference : **BR-2019-03 -** Type : **New**

Date: 16/01/2020

Adresse du siège: Adresse des locaux

TVA: FR 73 50 78 66 283

SIRET: 50 78 66 28 30 00 17 RCS ANTIBES

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 Bl001 & FA001 Containing Mela Peel Forte batch M01 and Activa Peel Forte batch L02 		
Primary clinical purpose of device	1 Devices are used by doctors in an in-clinic protocol of neeling		
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.

Directeur: N. Fagiuoli

Téléphone: + 33 04 86 87 24 20

Facsimile: + 33 04 86 87 24 21



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 ta	ble if you still hold the affected MDs (use an	excel sheet if insufficient space):				
MD nam		Batch number	Quantity				
	I have destroye	ed the above list of medical devices					
Quantity destroyed: Date of destruction:							
Date of d	estruction:						
Distributor Name:							
Date:							
Signature:							
2 3							
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	Activa Peel	L02	02/2019
	L02		L03	03/2019
		Mela Peel	L01	03/2019
Mela Peel Forte	BI001	Activa Peel Forte	L02	10/2020
Kit	FA001	Mela Peel Forte	M01	03/2020

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