Urgent: Field Safety Notice

For the attention of Distributors and Users of Manuka Wound Honey:

Date:	September 2024
FSCA Identifier:	24-0189-FSCA
Manufacturer	EctoMed
Product Name:	Manuka Health – Manuka Wound Honey
Product Description:	Manuka Wound Honey is a sterile tube filled product, and is designed to be used directly on cuts, grazes and minor burns, or used with a secondary dressing.
Product Code:	PR02748
Batch/Lot Number(s) Affected	2402334 / 2402337
Date of Manufacture	March 2024
UDI Number(s)	5060419550713
Issue	Initial Issue

Please note that this action only applies to product code PR02748 and LOT 2402334 and 2402337 of Manuka Wound Honey (30g)

Reason for Field Corrective Action:

Description of Issue	EctoMed the manufacturer of the Manuka Health - Manuka Wound Honey product are voluntarily initiating a field action for the above-stated affected product because it has been identified that the sterility of the products is not assured, and we cannot guarantee the sterile status in accordance with EU Medical Device Requirements.
Risks	The product is used on minor cuts, grazes and burns, and the use of the affected product may result in an increased risk of infection. Based on ongoing internal investigations the likelihood of this is considered low risk. However as a precautionary measure we require the disposal of the affected products detailed. We can confirm that there are no adverse events or complaints filed by users, customers or authorities, related to this issue. But we want to maintain the highest standards for the product and for end user safety and to proceed with the identification and disposal of the affected tubes on this basis. Only identified batches LOTS 2402334 and 2402337 are affected and subject to this field action.

Actions:

Product Identification

- Confirmation of Specific Product Code and LOT:
- This issue is limited to product code PR02748
- Only identified batches LOTS 2402334 and 2402337 are affected and subject to this field action.
- For this reason and to address any potential risk of harm, the affected products from LOTs 2402334 and 240337 should not be used.
- The way to identify the affected product is the LOT number printed on the tube and on the carton.

Distributor Actions:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Complete the attached Customer Response Form and return it to the address on the response form. **Return the attached Customer Response Form even if no affected product is in inventory.**
3	If you have distributed this product to other wholesalers, then forward this letter to them and ask that they follow these Distributor Actions and return the attached **Customer Response Form** to the address listed on the form.
4	Send a copy of this market action notification to all other consignees: Retailers, if applicable, and end users.
5	Send a complete list of all consignees to the EctoMed contact details identified at the end of this notification. This information is required to allow EctoMed to perform corrective action effectiveness checks.

Retailer Actions:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Complete the enclosed **Customer Response Form** and return it to the address on the response form. **Return the Customer Response Form even if no affected product is in inventory.**
3	Post page one of this Field Safety Corrective Action notice in a conspicuous location in your store.

End Users Actions:

1	Immediately stop use of the affected product
2	Dispose of the product and contact distributor to confirm disposal.

Transmission of this Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)
- Please transfer this notice to other organisations on which this action has an impact. (As appropriate)
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

EctoMed is committed to providing quality products and services to our customers and we sincerely apologise for any inconvenience this notice may cause.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

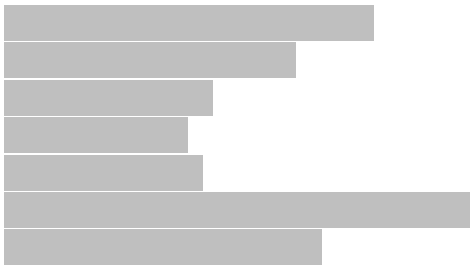
Authorisation:

Name	**Title**	**Address**	
	)		
Date		**Signature**	

Name	**Title**	**Address**	
Date		**Signature**	

Manufacturer contact details:

Local distributor contact details:



Attachment 1- Customer Response Form

1. We have reviewed and understood the Field Safety Notice, the information and actions have been bought to the attention of all relevant users:
   ☐ Yes
   ☐ No

2. All the customer actions have been completed
   ☐ Yes
   ☐ No Explain which actions have not been completed
   ……
   ……

3. Quantity of affected Devices at facility ……

Facility Name ……
Facility Address ……
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……

Name (Print) …… Title ……

Signature …… Date ……