Field Safety Notice

FSN Ref: FSN-01 **FSCA Ref**: FSCA-01

Date: 10:02:2022

Product Name: **Pharmagel breast Pads**

For Attention of*:All distributors of Pharmagel breast pads supplied by Pharmaplast SAE

Contact details of local representative (name, e-mail, telephone, address etc.)*
[redacted]

Risk addressed by FSN

1. Information on Affected Products*	
1.	1. Product Type(s)*
	Pharmagel Breast pad are made of hydrogel three-dimensional sheet casted on Non-woven backing material that control the leakage of exudates.
1.	2. Commercial name(s)
	Pharmagel Breast pads
1.	3. Unique Device Identifier(s) (UDI-DI) (For Medical devices)
	N/A
1.	4. Primary clinical purpose of medical device(s)* or intended purpose of PPE:
	Used to provide instant cooling relief from cracked, painful or sore nipples.
1.	5. Product Model/Catalogue/part number(s)*
	GEL7075
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Pharmaplast requested Gmed to withdraw "Pharmagel Breast pads" from CE certificate # 27236
2.	2. Hazard giving rise to the FSCA*
	products placed on the market that could demonstrate potential risk of an incident due to unanswered clinical and biological issues to the notified body Gmed SAS
2.	3. Probability of problem arising
	Remote
2.	4. Predicted risk to patient/users for medical device only.
	Pharmagel Breast pads may not be able to meet its clinical and biological properties
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Notified Body (Gmed) raised issues during a documentary audit regarding clinical evaluation and biological evaluations for Pharmagel Breast pads. Unable to meet timelines and financial requirements for multiple documentary audits, Pharmaplast requested Gmed to withdraw "Pharmagel Breast pads" from CE certificate # 27236 taking into account that the device conformtiy assessment based on directive 93/42/EEC shall not be valid beyond 26 May 2024.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*

3.	**1. Action To Be Taken by the User*** ☐ Identify product ☐ Quarantine product ☐ Return product ☒ Destroy product ☐ On-site product modification/inspection ☐ Follow patient/user management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	February 2022
3.	3. Particular considerations for: Choose an item. Is follow-up of patients/end users or review of patients'/end users' previous results recommended? Choose an item. Provide further details of patient/end user-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site product modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Product shall not be introduced into the EU market until conformity assessment is conducted	
3	6. By when should the action be completed?	N/A
3.	7. Is the FSN required to be communicated to the patient /end user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/end user in a patient/lend or non-professional user information letter/sheet? Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item.
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Confirmation of available stock disposal if present	
4	6. Anticipated timescale for follow-up FSN	February 2022
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Pharmaplast SAE**
	b. Address	**Amria free zone, 23512, Alexandria, Egypt**
	c. Website address	**www.pharmaplast-online.com**
4.	8. This Field safety note is coordinated with the Irish competent authority HPRA	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected products 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 product-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Signature Certificate

Reference number: [redacted]

Signer	Timestamp	Signature
[redacted]		[redacted]
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