PREVOR
PRÉVOIR ET SAUVER
Laboratoire de Toxicologie & Maîtrise du Risque Chimique

FSN Ref : NC 32171 v.1
Date : 05 MARCH:2025

FSCA Ref : NC 32171

URGENT FIELD SAFETY NOTICE

DIPHOTERINE® LP (LPD)

For the attention of Emergency Department and Burns Department managers

Contact details of local representative	
Distributed in Denmark by:	MEDICAL CARE SYSTEM MCS AB Industrivägen 5 64234 Flen SWEDEN Tel : +46 (0) 157 13131 Email contact : info@medicalcare.se

1. Information on Affected Devices*	
1.	***1. Device Type(s)****
	DIPHOTERINE® LP (LPD) Sterile solution for corrosive and irritant chemical splashes for ocular decontamination 
1.	***2. Commercial name(s)***
	DIPHOTERINE® LP
1.	***3. Primary clinical purpose of device(s)****
	Eye wash for corrosive and irritant chemical splashes. The purpose of the device is to wash away corrosive or irritant chemicals when they come into contact with the eye in order to eliminate the chemical that has not yet reacted with the tissue, thus avoiding or limiting its action. Therefore, the extent and severity of the chemical injury is avoided or limited and, if necessary, secondary care can be provided.
1.	***4. Device Model/Catalogue/part number(s)****
	LPD
1.	***5. Affected serial or lot number range***
	See Appendix 1

MOULIN DE VERVILLE - F95760 VALMONDOIS - TÉL : (33) 01 30 34 76 76 - FAX : (33) 01 30 34 76 70

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2. Reason for Field Safety Corrective Action (FSCA)*	
2.	***1. Description of the product problem****
	An anomaly on the label of the LPD device was detected by our staff. The anomaly consists in not having the intended use of the device available in Danish. Even though this information is available in English, users do not have access to the intended use in their local language. **LPD label** 
2.	***2. Hazard giving rise to the FSCA****
	The lack of Danish translation of the medical purpose on the LPD label creates the risk of not using the device.
2.	***3. Probability of problem arising***
	Since the intended use is available in English and the device is used in hospitals and pre-hospitals emergency services, the problem is unlikely to happen.
2.	***4. Predicted risk to patient/users***
	The risk associated for the patient user in not using the device is to delay the decontamination of the chemical splash. In such case, the chemical being longer onto the tissue, it has more time to act and could cause more severe chemical injuries.
2.	***5. Further information to help characterise the problem***
	The anomaly can be detected by visual examination of the label, seeking for the intended use in Danish. The text is missing.
2.	***6. Background on Issue***
	The anomaly was detected internally, by PREVOR's staff during a review of the label. No incident occurred so far related the lack of this information in Danish.
2.	***7. Other information relevant to FSCA***
	Intended use in English is correct and can be used.

	3. Type of Action to mitigate the risk*
3.	***1. Action To Be Taken by the User****
	☒ Take note of amendment of the LPD device label : The missing information in Danish on the device label concerns the intended use of the device.

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	The intended use is as follow : **"Eyewash for corrosive and irritant chemicals.** **Reduced efficacy on hydrofluoric acid and its derivatives."**	
3.	***2. By when should the action be completed?***	**31 MAR 2025**
3.	3. ***Is customer Reply Required?*** * **See Appendix 2** (If yes, form attached specifying deadline for return)	**Yes**
3.	**4. Action Being Taken by the Manufacturer** PREVOR provides the corrected label with the intended use in Danish to the Danish distributor. Danish distributor gives FSN to the customer. Danish distributor affixes the corrected label to each LPD concerned at customer's premises. Danish distributor asks to the customer to fill the form of appendix 2. Danish distributor collects customer reply form of appendix 2. Danish distributor sends to PREVOR the completed form.	
3	***5. By when should the action be completed?***	**30 APR 2025**
3.	***6. Is the FSN required to be communicated to the patient /lay user?***	**No**
3	***7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?***	
	N/A	

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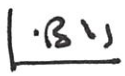
	4. General Information*	
4.	***1. FSN Type****	**New**
4.	***2. For updated FSN, reference number and date of previous FSN***	N/A
4.	***3. For Updated FSN, key new information as follows:***	
	N/A	
4.	***4. Further advice or information already expected in follow-up FSN? ****	**NO**
4	***5. If follow-up FSN expected, what is the further advice expected to relate to:***	
	N/A	
4	***6. Anticipated timescale for follow-up FSN***	N/A
4.	***7. Manufacturer information*** ***(For contact details of local representative refer to page 1 of this FSN)***	
	a. Company Name	**PREVOR**
	b. Address	Moulin de Verville Nesles la Vallée 95760 VALMONDOIS FRANCE
	c. Website address	**www.prevor.com**
4.	***8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. ****	
4.	***9. List of attachments/appendices:***	**Appendix 1 : List of batch numbers concerned** **Appendix 2 : Customer reply form**
4.	***10. Name/Signature***	**Joël BLOMET** ***Person responsible for regulatory compliance***
		

	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 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..*

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Appendix 1
LIST OF BATCH NUMBERS CONCERNED

DIPHOTERINE® LP
DV530506C
DV330907C
DV340401B
DV340520C

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Appendix 2
CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number*	NC 32171 v.1
FSN Date*	2025-03-05
Product/ Device name*	DIPHOTERINE® LP
Product code(s)	LPD

2. Customer Details	
Company name*	
Account number	
Adresse*	
Shipping address if different from above	
Contact name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken

- I confirm receipt of the Field Safety Notice and that I have read and understood its content. *(Tick the appropriate box)*
  Yes [ ] No [ ]
- I have performed all actions requested by the Field Safety Notice. *(Tick the appropriate box)*
  Yes [ ] No [ ]
- The information and required actions have been brought to the attention of all relevant users and executed. *(Tick the appropriate box)*
  Yes [ ] No [ ]

Name*	
Signature*	
Date*	

*Mandatory fields are marked with **

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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