Hubert De Backer nv

FSN Ref: FSN-23-0001

FSCA Ref: FSCA-23-0001

Date: 2023/11/15

Field Safety Notice
1 mL Dosing Applicator T2023+T2024

For Attention of*: [redacted]

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

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Field Safety Notice (FSN)
1 mL Dosing Applicator T2023+T2024

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	The involved device is a 1 mL Oral Dosing Applicator, which is a plastic dosing syringe consisting out of a barrel with a graduation scale printed onto it and a plunger. Below are two pictures of the involved device: 
1.	2. Commercial name(s)*
	FP0000 FLOWPACK T2024 ORALE APPLICATOR PLUNGER 1 ML T2023 ORALE APPLICATOR BARREL 1 ML
1.	3. Primary clinical purpose of device(s)*
	The 1 mL oral dosing applicators are intended to be used for the administration of a medicine to the human body through the mouth.
1.	4. Device Model/Catalogue/part number(s)*
	[redacted] Product Description: Kolbendosierpipette 1 ml (geteilt in 0,05 ml) Product Reference: 032401
1.	5. Affected serial or lot number range
	• 22-2084/00 • 22-2493/00 • 22-2570/00

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Contamination (the investigation indicates that the contamination comes from ink residues that contaminated the printing machine which led to the contamination of the products)
2.	2. Hazard giving rise to the FSCA*
	When the contamination is not noticed by the user and a contaminated dosing applicator is used, the contamination could enter the body and could potentially cause a serious deterioration of the patient's health.
2.	3. Background on Issue
	We received a notification from the German CA that a User Report had been submitted related to contaminated 1 mL dosing syringes in our Batch 22-2493/00. Earlier we had received a complaint about this from our customer, but it was not considered as a serious incident. Following the notification a MIR type Final (Non-reportable incident) was provided to the German CA. Additional questions were asked by the German CA and answered. At the same time a second User Report had been submitted related to contaminated 1 mL dosing syringes in our Batch 22-2570/00. The German CA informed us of the recurrency of the device issue "contamination" and informed us that they consider the issues as a serious incidents.

3. Type of Action to mitigate the risk*		
3.	1. **Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device A recall of the before mentioned affected batches (lot numbers) has to be performed.	
3.	2. By when should the action be completed?	As soon as possible
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	4. **Action Being Taken by the Manufacturer*** ☒ Product Removal The returned products will be destroyed.	
3.	5. By when should the action be completed?	As soon as possible
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

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4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Hubert De Backer nv
	b. Address	Laagstraat 59, 9140 Temse, Belgium
	c. Website address	www.hdb.be
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. Name/Signature	Stijn De Backer General Manager

	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.*

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

Field Safety Notice - Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-23-0001
FSN Date*	15/11/2023
HDB Product/ Device name*	1 mL Dosing Applicator T2023+T2024
WEPA Product Description	Kolbendosierpipette 1 ml (geteilt in 0,05 ml)
WEPA Product Reference	WEPA Product Reference: 032401
Batch Numbers	• 22-2084/00 • 22-2493/00 • 22-2570/00

2. Distributor/Importer Details	
Company Name*	[redacted]
Account Number	
Address*	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	quality.systems@hdb.be
Distributor Helpline	+32(0)3 776 34 94
Postal Address	Laagstraat 59 9140 Temse Belgium
Deadline for returning the Distributor reply form*	Please conform (at least) the reception and understanding (first checkbox) within one week, and provide updates of the form according to what has been performed.

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	

☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
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.