

Field Safety Notice (FSN)

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1. Other information on affected device

Inconsistent results with following products due to cartridge reagent defect

Product device Name	AD reference	Lot Number	Quantity received	Date of shipment – delivery note
NDH Chromatin + DFS70 Dot for BDI	ADNDHDFSDBD	FA240518	12	04-06-2024 / 20240236

2. Reason for Field Safety Corrective Action

Risk of inconsistent results with the products

3. Type of Action to mitigate the risk

Action(s) to be taken by the manufacturer

- Identify non-conforming products already distributed : 12 units
- Identify non-conforming product remaining in stock: 0 unit
- Destroy non-conforming product remaining in stock: not applicable.

When the action have to be done : 26-06-2024

This FSN requires to be communicated to the distributors/importers concerned and will be supplied with Field Safety Notice – Distributor Importer Reply Form (Appendix 1)

Action(s) to be taken by distributors and sub-distributors

- Identify non-conforming products already distributed
- Identify non-conforming product remaining in stock
- Destroy non-conforming product remaining in stock
- Advice sub-distributors and end-user with FSN

If applicable, this FSN requires to be communicated to the customers and end-user concerned and will be supplied with Field Safety Notice – Customer-End-user Reply Form (based on Appendix 2)

This Reply Form is supplied in English with this FSN, please translate this template into the languages required by applicable regulation for the end-users.

Action(s) to be taken by customers-end-users

- Identify non-conforming products already used
- Identify non-conforming product remaining in stock
- Destroy non-conforming product remaining in stock

4. Other information

*The Competent (Regulatory) Authority of your country has been informed about this communication to customers. **

Appendix 1: Template for a Field Safety Notice Distributor/Importer Reply Form

Appendix 2: Template for a Field Safety Notice Customer Reply Form Customer/End-User Reply Form

Note: Please refer to the document **md_sector_lang-req-table-ivdr** sent with this advisory notice for the translation requirements of the FSN template in European countries, please refer to your importers or authorized representative persons for the requirements in other countries.

We apologize for any inconvenience caused and remain at your disposal for any further information. Please contact our RA Manager, if needed.

Bernard Noirhomme QA Manager	
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This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations 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.*

Appendix 1 - Template for a Field Safety Notice Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number		SQP240621-1		
FSN Date		21-06-2024		
Product device Name	AD reference	Lot Number	Quantity received	Date of shipment – delivery note
NDH Chromatin + DFS70 Dot for BDI	ADNDHDFSDDBD	FA240518	12	04-06-2024 / 20240236

2. Distributor/Importer Details	
Company Name	RuWag
Address	Bielstrasse 52 2544 Bettlach SWITZERLAND
Contact Name	Christine Von Landenberg
Telephone number	+41 32 644 27 27
Email	christine.vonlandenberg@ruwag.ch

3. Return acknowledgement to Sender	
Email	noirhomme.b@alphadia.be , bonnet.m@alphadia.be contact@alphadia.be
Distributor/Importer Helpline	+3210685610
Postal Address	15A, Rue du Bosquet – 1435 Mont-Saint-Guibert BELGIUM
Web Portal	
Deadline for returning the Distributor/Importer reply form	27-06-2024

4. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete
☐	I have checked my stock and quarantined inventory	Distributor/Importer to complete (enter quantity) and date
☐	I have identified customers that received or may have received this device	Distributor/Importer to complete
☐	I have informed the identified customers of this FSN	Distributor/Importer to complete
☐	I have received confirmation of reply from all identified customers	Distributor/Importer to complete
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date destroyed
Print Name		Distributor/Importer to complete
Signature/ Stamp		
Date		

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.

Advisory Notice

Appendix 2 - Template for a Field Safety Notice Customer/End-User Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number		SQP 240621-1		
FSN Date		21-06-2024		
Product device Name	AD reference	Lot Number	Quantity received	Date of shipment – delivery note
NDH Chromatin + DFS70 Dot for BDI	ADNDHDFSDBD	FA240518	12	04-06-2024 / 20240236

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Shipping address if different to above	
Contact Name	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content		
☐	I performed all actions requested by the FSN		
☐	The information and required actions have been brought to the attention of all relevant users and executed		
☐	I have destroyed affected devices – enter number destroyed and date complete	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for destruction		
Print Name			
Signature			
Date			

4. Return acknowledgement to sender	
Email	
Postal Address	
Web Portal	
Deadline for returning the customer reply form	26-07-2024

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.