Date: 2024-11-14

Field Safety Notice
DENTASEPT SPRAY 60 PRO

For Attention of*: Vigilance/Quality manager of the facility products.

Dear customer,

We have noticed that you have been delivered products with incorrect information on the label. The products in scope of this FSN are as follows:

Product Name	Packaging	SKU
DENTASEPT SPRAY 60 PRO	1x5L	2475042BO/ECL3126690
	3x1L	2475500BL/ECL3126700

Please kindly request you to review the information in this document and follow the appropriate actions outlined in section 3.

We sincerely apologize for any inconvenience this may cause and appreciate your understanding and cooperation in this matter.

Thank you for your cooperation and understanding.

Best regards,

ECOLAB VIGILANCE
On behalf of D.M.D

Field Safety Notice (FSN)

1. Information on Affected Devices	
1.	1. Device Type(s)
	Medical devices
1.	2. Commercial name(s)
	DENTASEPT SPRAY 60 PRO
1.	3. Primary clinical purpose of device(s)
	Technical performance- No direct clinical purpose
1.	4. Device Model/Catalogue/part number(s)
	All the batches of the following references:

Product Name	Packaging	SKU
DENTASEPT SPRAY 60 PRO	1x5L	2475042BO/ECL3126690
	3x1L	2475500BL/ECL3126700

2. Reason for Field Safety Corrective Action (FSCA)

2. 1. Description of the product problem

Laboratoires Anios was informed by a distributor of the incorrect translation in Romanian of some instructions on the labels of a disinfectant product.

Laboratoires Anios also completed a review for D.M.D which a dental medical devices legal entity for Laboratoires Anios.

The Romanian translation of the contact times for fungicidal and tuberculocidal activities was incorrect on the labels of Dentasept Spray 60 Quick.

There is therefore a risk of inadequate disinfection, which could lead to cross-contamination and infection in high-risk patients. D.M.D is recalling the affected products distributed in Romania, and updating the labels and all accompanying information for the products concerned.

Please be aware that the errors are limited to SKUs mentioned in the table below.

Product Name	Packaging	SKU	Errors in Romanian
DENTASEPT SPRAY 60 PRO	1x5L	2475042BO/ ECL3126690	Fungicidal acc. to EN13624*/EN17387* in 5 sec. (instead of 5 min) Tuberculocidal acc. To EN 14348* in 30min. (instead of 30 sec.)
	3x1L	2475500BL/ ECL3126700	

2. 2. Hazard giving rise to the FSCA

This might lead to a risk of cross contamination and infection in high-risk patients.

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the User In Romania

☒ Identify Device

☒ Destroy the device

☒ Inform all users within your facility

☒Fill in the customer reply form

3.	**2. Action To Be Taken by the Distributor In Romania** ☒ Identify Device ☒ Destroy the device ☒ Inform all customers about the actions to be taken ☒Fill in the customer reply form	
3.	3. By when should the action be completed?	Immediately
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes attached
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None All new batches have been produced with new labels.	

4. General Information			
4.	1. FSN Type	New	
4.	2. Further advice or information already expected in follow-up FSN?	No	
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)		
	a. Company Name	D.M.D	
	b. Address	1 RUE DE L'ESPOIR 59260 LEZENNES FRANCE	
	c. Website address	www.anios.com	
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.		
4.	5. List of attachments/appendices:	FSN Reply Form;	
4.	6. Name/Signature	Quality Director Europe	
		(Senior Regulatory Affairs 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.