1 rue de l'Espoir
59260 LEZENNES
France
Tel +33 3 20 67 67 67
Fax + 33 3 20 67 67 68
Email Vigilance@anios.com

To Healthcare Organisation Name
Address

URGENT
FIELD SAFETY NOTICE

Date: 2020/06/12

Object:

☒ *Batch recall*
☐ *Information and/or recommendations*

Affected products:

Device Commercial Name	Batch	Packaging	Article Code
QUITANET ULTRA	C02414S	12 X 1L	2762092L6

Madam, Sir,

We have been informed by the Spanish Health Authorities, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), that the batch of raw material chlorhexidine digluconate used in the manufacturing of the above batch of finished goods has been identified as contaminated by a Gram negativ bacteria compatible with Enterobacteria.

Although all batches of QUITANET ULTRA passed the quality and microbiological release tests at the manufacturing site at D.M.D., AEMPS requested for the recall of the batch C02414S of QUITANET ULTRA marketed in Spain.

In consequence, we ask that you stop immediately using the recalled products that you may have in stock, to block and isolate these products. In addition, we need you to inform immediately your end customers and ask them to notify you of the quantities they have in stock. You will be required to collect the completed response form (Annex I) from your customers and share a consolidated form with us of all the products you have recalled to the following e-mail address: Vigilance@anios.com. Any quantity declared can be subject of verification.

Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 10/07/2020 - the completed and signed reply form.

Your D.M.D. representative will contact you to discuss the return of the recalled product you have in stock.

We remain at your entire disposal for any question or assistance that you may need.

D.M.D
Division des Laboratoires ANIOS

The undersigns confirm that this notice has been reported to the appropriate Regulatory Agency.

Please accept our apologies for the inconvenience it may have caused.

Yours faithfully

Marc Grenier *Quality Manager*	Dr Monique Manche *Materiovigilance Contact Person*	Pierre-Marie Marcelet *President*
		

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

This means, if you are a distributor, that this information has to be forwarded to any customers which was delivered with one of the affected batches.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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ANNEX I
CUSTOMER REPLY FORM

1. **Field Safety Notice (FSN)**

FSN Reference: FSN_DMD_CHG_EN_QUITANET ULTRA

FSN Date: *2020/06/12*

Affected products:

Device Commercial Name	Batch	Packaging	Article Code
QUITANET ULTRA	C02414S	12 X 1L	2762092L6

2. **Customer Details**

Customer Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	
Print Name*	
Signature*	
Date*	

Mandatory fields are marked with *

D.M.D
Division des Laboratoires ANIOS

3. Customer action undertaken on behalf of Healthcare Organisation

☐ I confirm receipt of the Field Safety Notice (FSN) 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, including end customers in case of distribution of those products

☐ I informed the supplier of the stock I have that is subject of the recall and needs to be returned

PERSON OF CONTACT FOR RETURN OF GOOD: _____

EMAIL OF CONTACT: _____

PHONE NUMBER OF CONTACT: _____

Device Commercial Name	Article Code	Batch N°	Packages Quantity (units)

☐ No affected devices are available for return

☐ Other Action (Define):

4. Return acknowledgement to sender

Email	Vigilance@anios.com
Postal Address	D.M.D. Service qualité 1, rue de l'Espoir 59260 Lezennes - France
Fax	+33 3 20 67 67 68
Deadline for returning the customer reply form	10/07/2020

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