*Pavé du Moulin*
*59260 Lille-Hellemmes*
*Tel +33 3 20 67 67 67*
*Fax + 33 3 20 67 67 68*
web *vigilance@anios.com*

To Healthcare Organisation Name
Address

# URGENT
# FIELD SAFETY NOTICE

*Date: 22/01/19*

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

*Affected products:*

| Device Commercial Name | Article Code | Packaging |
|---|---|---|
| WIP'ANIOS PREMIUM | 2088655BR /2088655C4 / 2088655C5 | 6 X 100 WIPES |
| WIP'ANIOS EXCEL | 2446424C2 /2446424ZA | 12X50 WIPES |
| | 2446492GX | 12X60 WIPES |
| | 2446655C4 / 2446655C5 / 2446655CO / 2446655Y6 | 6 X 100 WIPES |

Madam, Sir,

A microbial contamination source has been identified and localized in an outsourced manufacturing process and has brought a potential bacterial contamination to some batches of manufactured wipes.

In case of contamination triggered by contaminated wipes, immunocompromised patients would be at greater risk of infection. Globally, the risk assessment for potential health hazard linked to the use of those wipes results in low risk for the patient and the user. It takes into consideration the products' indication, the absence of any adverse event report linked to the use of the wipes, the probability of infection occurrence and the results of additional investigations (limited survival time of the bacteria on surfaces and sensitivity of this bacteria to antibiotics: piperacilline (PTZ) and ceftazidime (CZD).

Corrective actions to eliminate the contamination source have been implemented and are being closely monitored.

For precautionary reasons, we ask you not to use any longer any remaining units you may have in stock bearing the batch numbers documented in the enclosed appendix, as they may contain some contaminated wipes.

We would be grateful if you could acknowledge receipt of the present communication by returning at your earliest convenience - but no later than 28/02/2019 - the attached reply form duly completed and signed.
If applicable, the proof of product's destruction has to be provided to close the current action.

Your sales contact remains at your entire disposal for any question or assistance that you may need.

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

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

Yours faithfully

| Isabelle Prévost<br>*Quality Manager* | Dr Monique Manche<br>*Materiovigilance responsible* | Bertrand Letartre<br>*CEO* |
|---|---|---|
|  |  |  |

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.

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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*Tel +33 3 20 67 67 67*
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Healthcare Organisation Name
Address

# APPENDIX I
# CUSTOMER REPLY FORM

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

FSN Reference number: FSN_ANIOS_EN

FSN Date: *January 22, 2019*

*Affected products:* ***Please refer to appendix 2***

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 *

### 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 have destroyed affected devices – number of devices destroyed is documented in the table below (proof of destruction have to be provided to close the current action)

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

☐ No affected devices are available for destruction

☐ Other Action (Define):

### 4. Return acknowledgement to sender

| | |
|---|---|
| Email | vigilance@anios.com |
| Postal Address | Laboratoires ANIOS<br>Service qualité<br>Pavé du Moulin<br>59260 Lille – Hellemmes - France |
| Fax | +33 3 20 67 67 68 |
| Deadline for returning the customer reply form | 28/02/2019 |

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

# APPENDIX 2

# AFFECTED PRODUCTS

| Medical device name | Model | Reference number | Lot/batch number |
|---|---|---|---|
| WIP'ANIOS EXCEL | 12 packs of 50 wipes | 2446424C2 | A00324S |
| | | | A04420S |
| | | | A06805S |
| | | | A08122S |
| | | | A21502S |
| | | | A23602S |
| | | | A25015S |
| | | | A26503S |
| | | | A28107S |
| | | | W01716S |
| | | | W02615S |
| | | | W04204S |
| | | | W07004S |
| | | | W17911S |
| | | | W19303S |
| | | | W25811S |
| | | | W26321S |
| | | 2446424ZA | A00807S |
| | | | A23602S |
| | 12 packs of 60 wipes | 2446492GX | A12712S |
| | | | A20701S |
| | | | A26215S |
| | | | W33121S |
| | 6 packs of 100 wipes | 2446655C4 | A02518S |
| | | | A02615S |
| | | | A03211S |
| | | | A04305S |
| | | | A06805S |
| | | | A07305S |
| | | | A14911S |
| | | | A16210S |
| | | | A17404S |
| | | | A18712S |
| | | | A19311S |
| | | | A20108S |
| | | | A20409S |
| | | | A23320S |
| | | | A23602S |
| | | | A24126S |
| | | | A28107S |
| | | | W00513S |
| | | | W03015S |
| | | | W04204S |
| | | | W06116S |
| | | | W06823S |
| | | | W07917S |
| | | | W08310S |
| | | | W09318S |

# APPENDIX 2

# AFFECTED PRODUCTS

| Medical device name | Model | Reference number | Lot/batch number |
|---|---|---|---|
| | | | W13516S |
| | | | W14205S |
| | | | W15010S |
| | | | W15111S |
| | | | W16619S |
| | | | W17823S |
| | | | W20720S |
| | | | W21215S |
| | | | W23603S |
| | | | W23804S |
| | | | W24717S |
| | | | W25104S |
| | | | W25811S |
| | | 2446655C5 | A00807S |
| | | | A02615S |
| | | | A06805S |
| | | | A16210S |
| | | | A19311S |
| | | | A28107S |
| | | | W03015S |
| | | | W04722S |
| | | | W12423S |
| | | | W25603S |
| | | | W29906S |
| | | | W34720S |
| | | | W35612S |
| | | 2446655CO | W03015S |
| | | 2446655Y6 | A24126S |
| | | | A24712S |
| | | | A24829S |
| WIP'ANIOS PREMIUM | 6 packs of 100 wipes | 2088655BR | W01618S |
| | | | W03821S |
| | | | W18418S |
| | | | W26111S |
| | | 2088655C4 | A00219S |
| | | | A18104S |
| | | | A19123S |
| | | | U08405S |
| | | | U11821S |
| | | | U17703S |
| | | | U21512S |
| | | | U25702S |
| | | | U32001S |
| | | | W01618S |
| | | | W03821S |
| | | | W10912S |
| | | | W18418S |
| | | | W20304S |

# APPENDIX 2

# AFFECTED PRODUCTS

| Medical device name | Model | Reference number | Lot/batch number |
|---|---|---|---|
| | | | W24313S |
| | | | W26111S |
| | | | W29209S |
| | | | W35214S |
| | | 2088655C5 | A00219S |
| | | | A05504S |
| | | | A06105S |
| | | | A18104S |
| | | | A19123S |
| | | | A19725S |
| | | | U06705S |
| | | | U08405S |
| | | | U08412S |
| | | | U17605S |
| | | | U21404S |
| | | | U21512S |
| | | | U25602S |
| | | | U25702S |
| | | | U32001S |
| | | | U33419S |
| | | | U36401S |
| | | | W01618S |
| | | | W04410S |
| | | | W10104S |
| | | | W10912S |
| | | | W12905S |
| | | | W14705S |
| | | | W18418S |
| | | | W20304S |
| | | | W24313S |
| | | | W26111S |
| | | | W29209S |
| | | | W35214S |