*03/05/22*

# URGENT FIELD SAFETY CORRECTIVE ACTION

***ACCUFUSER 300ML 10ML/HR TA***

RA-049 Issue 1

**FSCA – Identifier: *2204/46905/00***

**Type of Action: *RECALL DEVICE***

**Details of Affected Devices:**

|  |  |
| --- | --- |
| **Product Code:** | **Batch/Lot** |
| VAWC0100L-TA | 1B0K113 |
| VAWC0100L-TA | 1B1C126 |
| VAWC0100L-TA | 1B0K61 |

### Description of Problem

During a documentation review Vygon (UK) Ltd have identified that there is no Document of Conformity (DOC) for the TA version (code: VAWC0100L-TA) of the C0100L Accufuser range held by the Legal Manufacturer. On further investigation with the legal manufacturer, it has been identified that code: VAWC0100L-TA is not listed on their CE certificate and does not have a Technical File.

It has therefore been agreed with the Legal Manufacturer that the product should be recalled from the market.

### Field Safety Corrective Action Instructions:

### Advice on action to be taken by Medical Staff

1. Identify and quarantine any remaining stock of the affected product codes and batch/lot numbers.
2. If you do not have stock from the affected batch number, stated above, mark the according checkbox on the enclosed FSCA Email Back Form, complete the form and send it to the following email address: technical@vygon.co.uk
3. If you have stock from the affected batch number, stated above, mark the according checkbox on the enclosed FSCA Email Back Form, provide the additional information requested and send the completed form to the following email address: technical@vygon.co.uk
4. On receipt of the completed FSCA Email Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements.
5. Please complete these actions by 31st May 2022.



### Instruction for Distributors of affected batch numbers

Please identify and quarantine any remaining stock of the affected product codes and batch/lot numbers in your warehouse(s), complete the FSCA Email Back Form and send the completed form to technical@vygon.co.uk. On receipt of the completed FSCA Email Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements.

As a distributor, please provide this Field Safety Corrective Action (FSCA) to all your customers who have received stock of the affected product codes and batch numbers, as stated above. Please send your customers the following documents:

* A copy of this Field Safety Corrective Action
* A copy of the FSCA Email Back Form

The FSCA Email Back Form should be completed by your customer and returned to you.

As a distributor you are required to confirm to Vygon (UK) Ltd that you have completed the instructed activity for all of your customers affected by this Field Safety Corrective Action. Please provide confirmation via email to technical@vygon.co.uk.

Please complete these actions by 31st May 2022.

### Vygon (UK) Ltd

Vygon (UK) Ltd has informed all customers, employees of Vygon (UK) Ltd and distributors of this Field Safety Corrective Action.

### Transmission of this Field Safety Corrective Action

This notice needs to be passed on to all recipients/users of this product within your organisation, in particular, the following:

* **All** departments/wards
* Pharmacies
* MHRA Liaison Officer
* Risk Managers
* Medical Device Safety Officer
* Medical Directors
* Nursing Directors
* Procurement

Please consider end users, clinicians, risk managers, supply chain/distribution centers etc. in the circulation of this FSCA.

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

### Contact Person

Kate O’Connell

Technical Support Department Vygon (UK) Ltd

The Pierre Simonet Building V Park, Gateway North Latham Road

Swindon

Wiltshire

SN25 4DL

Telephone: 01793 748800

Email: technical@vygon.co.uk

Vygon (UK) Ltd apologise for any inconvenience this FSCA may cause. This FSCA has been communicated to the MHRA.



Kate O’Connell

Technical Support Manager

E-mail: kate.oconnell@vygon.co.uk ; technical@vygon.co.uk

# FSCA EMAIL BACK FORM

### FIELD SAFETY CORRECTIVE ACTION REF. NO: *2204/*46905/00

### DATE: 03/05/2022

**Details of Affected Devices:**

|  |  |
| --- | --- |
| **Product Code:** | **Batch/Lot** |
| VAWC0100L-TA | 1B0K113 |
| VAWC0100L-TA | 1B1C126 |
| VAWC0100L-TA | 1B0K61 |

Please complete this form even if you do not have any affected product listed above and email the completed form to technical@vygon.co.uk

I/we acknowledge receipt of the above FSCA, and that the information contained in this FSCA has been shared with all recipients/users of the above products within our organisation.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name: |  |  | Mr/Mrs/Miss/Other: |  |
| Designation: |  |  |  |
| Organisation: |  |  |  |
| Department: |  |  |  |
| Address: |  |
|  |  |
|  |  |  | Post code: |  |  |
| Telephone No: |  |  | E-mail: |  |  |
| Signature: |  |  | Date: |  |  |

We do not have any of the affected stock listed above

We have the following stock remaining

|  |  |  |  |
| --- | --- | --- | --- |
| **Product Code** | **Batch/Lot Number** | **Quantity** | **Name of Supplier** |
| VAWC0100L-TA | 1B0K113 |  |  |
| VAWC0100L-TA | 1B1C126 |  |  |
| VAWC0100L-TA | 1B0K61 |  |  |

On receipt of this completed form, a representative of Vygon (UK) Ltd will contact you to arrange the return and replacement of affected stock.