Wyvern Medical Ltd
85a Ashford Road,
Eastbourne,
East Sussex BN21 3TE
Tel: 44 (0) 1531 631105

Urgent Field Safety Corrective Action Notice

Saliveze Dry Mouth Spray

Moi-stik

FSCA-identifier - FSCA 21/06/2023
URGENT Field Safety Corrective Action.

Date: 21/06/2023

Attention: All Customers, Wyvern Medical Ltd has issued a voluntary Field Safety Corrective Action, as it has been brought to our attention by the contract manufacturer of the above products that a certain batch has not met the necessary quality threshold. Our records indicate that you have received some of the products that may be effected.

We request that with immediate effect all the products below are quarantined and not passed on to customers.

Details on affected devices:
Saliveze Dry Mouth Spray - Lot Number 42151/09
- Exp Date: March 2026
- Dispatch Period 25/05/23 - 15/06/23

Saliveze Dry Mouth Spray - Lot Number 42151/10
- Exp Date: April 2026
- Dispatch Period 07/06/23 - 15/06/23

Moi-stik - Lot Number 41320/05
- Exp Date: Jan 2025
- Dispatch Period 08/06/23 - 15/06/23

Description of the problem and immediate action required:
The above products were dispatched to our warehouse prior to some of the normal test results being reviewed by the contract manufacturers QA department. This is contra to the agreed procedure. A subsequent review of the Bioburden test results and a re-testing of the same batch confirms that some of the above products have not met the necessary standards.

It appears that there was an issue with the sterile water used in this batch. A full investigation is underway. Therefore, in the interest of safety, we are asking all customers to RECALL the above products with immediate effect and arrange collection by Wyvern Medical.

We also require customers to provide us with details of their onward customers and also send to them a copy of this FSCA report to them.

Forwarding of this Field Safety Corrective Action:
This notification should be forwarded to all persons who need to be informed within your institution or in another company to which the products concerned have been transferred.

If applicable, include end users, doctors, nurses, risk managers, supply chain/distribution centres, etc. in the distribution list for this Field Safety Corrective Action.

Communication with end users:
All end users should be asked to cease using the products with immediate effect and dispose of the products locally.

Other Batches of the above products:
Please note, it is only the above batch numbers that are effected by this FSCA. All other products remain unaffected and require no action.

Please confirm receipt of this notification by returning the feedback form attached by e-mail no later than 22 June 2023

Contact:
Should you require further information or assistance regarding this FSCA please contact

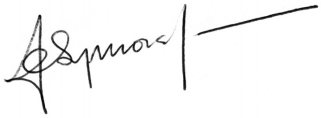
Wyvern Medical Customer Services - 01531 631105 email: info@wyvernmedical.co.uk

Wyvern Medical is committed to providing high quality, safe and effective products which is why we have issued this voluntary FSCA prior to the final test results being known. This is the first time a Fail has been reported in >20 years of production of the above products.

We expressly apologise for any inconvenience this may cause you.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Signature



Mr JC Sijmonsbergen
QA Manager - Wyvern Medical Ltd

Confirmation Notice

Field Safety Corrective Action FSCA 21/06/2023

Saliveze Dry Mouth Spray
Moi-stik

Customer Name/Address:

Please fill out this form and send it by e-mail to info@wyvernmedical.co.uk

For Medical Facility:

☐ **We acknowledge receipt of this Field Safety Corrective Action and have identified and disposed of the above products.**

For Distributors

☐ **We acknowledge receipt of this Field Safety Corrective Action and will arrange the return of the above products. We have forwarded the Field Safety Corrective Action to our customers and asked they remove and dispose of any of the above products.**

Full Name: _____

Email: _____

Tel: _____

Date/ Signature _____