bimed
TEKNİK ALETLER SAN. ve TİC. A.Ş.

URGENT Field Safety Notice – Product Recall

Manufacturer Incident Ref.	20231001 – 3Dose Syringe	Manufacturer	Bimed Teknik Aletler
Product Codes	3DG125, 3DO100	Batch Numbers	22A178B, 22F018B, 22B218B, 22L128B
Date	18 Apr 2023	Document	VMR2238-FSN-2023-04-18-v4-EN

Dear User of 3Dose Syringes,

The legal manufacturer BIMED TEKNIK ALETLER A.S. has issued a Field Safety Corrective Action (FSCA) for the recall of 3Dose products.

We – Vlow Medical B.V. European distributor - request your kind cooperation - on behalf of the manufacturer - for the recall of the affected products.

This URGENT Field Safety Notice is intended to notify the following:

1. The nature of the problem

Products produced since April 2022 does not comply with the requirements for current CE marking and therefore are not fit for sale and will be recalled.
The quality and reliability of the product have not changed; the issue is solely related to documentation errors.

2. Affected Products

The affected batch numbers are:
- 22A178B, 22F018B, 22L128B (Product code:3DG125 - Green syringes)
- 22B218B (Product code: 3DO100 - Orange syringes)

3. Measures to be taken by the customer/user

a) Do not use batches 22A178B, 22F018B, 22L128B, 22B218B
b) Identify any remaining stock of the above mentioned batches in your inventory and return any remaining product not used
c) Complete and return the attached form immediately to acknowledge receipt of the URGENT Field Safety Notice letter, as well as your understanding of the problem and required actions to take.

This communication has been forwarded to the competent Authorities.

Vlow apologizes for any inconvenience this issue may cause.

Best regards,

Vlow Medical B.V.
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5642 JC Eindhoven
The Netherlands