

URGENT FIELD SAFETY NOTICE

Product/s: **3EnzySponge (Code: BSC-ECS-....)**
NeutralCleanerSponge (Code: BSC-NCS-....)

The purpose of this letter is to advise you that mdd Company GmbH is voluntary performing a Field Safety Corrective Action for the above mentioned products and for the lot as listed here below:

Lot.: 18B999MS01

Reason for this Field Safety Notice:

A contamination of both products referred to the above mentioned lot has been discovered. After an internal lot control and the confirmation from a customer we discovered the contamination of both products as listed above.

The internal investigation to know the causes of this contamination is still ongoing.

Risk to health:

Due to the nature of the products and its intended use (pre-cleaning of flexible instruments) the internal Health Hazard Evaluation has concluded that the use of the contaminated products is not likely to cause adverse health consequences. Nevertheless our company cannot allow the contaminated product will be used in any case.

To avoid that any units of BSC product will be used again, please, follow the advise on action to be take by the distributor and the users:

1. Review the inventory of both products (3EnzySponge and NeutralCleanerSponge) to know where each unit is.
2. Re-call all units not stored in your warehouse.
3. Store all units of the above mentioned products and lots till all units are re-called and arrived in your warehouse.
4. If the affected products have been further distributed within or beyond your organization, please ensure that this information is forwarded to the distributor(s) or to user(s) of the device.
5. Stop immediately each sale of these products.

Further Preventive Actions:

1. All products must be stored in a specific area of the warehouse with clear information for all operators that it cannot be used or shipped.
2. After the complete re-call of all units you will receive exact instruction for the next steps.

Beghetto Gianluca



PLEASE COMPLETE AND RETURN THIS FORM AS SOON AS IS POSSIBLE

Send the scanned document in .pdf format to this email: info@mddcompany-gmbh.com

OR fax the document to: **+39 02 700430829**

Or send the original document by mail to:

mdd Company GmbH – Rengglochstrasse, 38 – CH-6012 Obernau – Switzerland

FIELD SAFETY NOTICE RETURN RESPONSE

Acknowledgment & Receipt Form

Response Required

Customer information: (Customer Name)

(Attn)

(Address)

Product/s: 3EnzySponge (Code: BSC-ECS-....)

NeutralCleanerSponge (Code: BSC-NCS-....)

I have read and understood the attached Field Safety Notice instructions:

(Name)_____

Responsible members have been informed of the need to discontinue the use of 3EnzySponge and/or NeutralCleanerSponge and to send back all the remaining units.

Yes ☐

Have any adverse events associated with the product been reported?

Yes ☐ No ☐

If yes, please explain:

AFFECTED PRODUCT INFORMATION:

Product	Product Code	Lot Number	Quantity Ordered	Quantity Used	Quantity Destroyed/Returned
3EnzySponge	BSC-ECS-200	18B999MS01			
NeutralCleanerSponge	BSC-NCS-250	18B999MS01			