Field Safety Notice **Recall letter for end users**		Diffuplast S.r.L. Via Piave 48, 21057 Olgiate Olona (VA), Italia

2 March 2021

Dear Baxter SA,

Diffuplast has been informed by its EO sterilization supplier that, after an internal review, the sterilization certificates received by Diffuplast differs from the original raw data.

The involved medica! devices are:

Product name	Code	Batch
Exacta Mix	E1420OD	M006FE
ExactaMix	El320OLPF	M006CE
Filling set	H9380003	M006ZA
ExactaMix	E1420OD	M0llFE
ExactaMix	E1420OD	M014FE
ExactaMix	E1440OD	M016FG
ExactaMix	E1420OD	M016FE

Based on the analysis of the original raw data, we can provide the following information: only the preconditioning cycle was affected, while the sterilization cycle and degassing cycle have been performed correctly, all the biological indicators have been processed correctly and all of them are sterile (no growth of the test organism). Therefore, further investigation is required before the release of batches.

While waiting for the investigation to be completed, as a precaution, please stop the distribution of the involved products until further notice and perform the recall *of* the involved batches from end users.

To implement this recall, please perfom the following actions:

1. Examine Your inventory and quarantine the affected products.
2. Discontinue the use and distribution of batch numbers listed above.
3. Inform Diffuplast of the quantity of affected medical devices in Yourstock.
4. In case You have already distributed some of the affected products, please identify Your customers and notify them of this product recall.
5. Please provide an acknowledgement form to Your customers to complete and return to You to track the numbers of devices in stock or used.
6. Please request Your customers to return the affected devices and quarantine them.
7. This recall should be carried out to the final customer level.

Diffuplast has sent an FSCA report to the relevant National Competent Authorities.

Your assistance is sincerely appreciated. Diffuplast apologizes for any inconvenience that this recall may cause to You and Your staff.

If You any question, please do not hesitate to contact us at number +390331640646 or write to info@diffuplast.it.

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Diffuplast S.*r.l.*