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Recall letter

November 22th, 2018

Dear Valued Customer,

This letter is to inform You that Diffuplast S.r.l is voluntarily recalling three batches of its Class-I sterile medical devices, according to Rule 2 of Directive 93/42/EEC Annex IX, as amended by Directive 2007/47/EC.

The affected products are:

- Code E1402OD, batch H069FB
- Code E1405OD, batch H069FC
- Code E1405OD5, batch H071NC

This recall has been initiated due to the discovery of the leakage of some bags. The probability of occurrence of the leakage is low, yet Diffuplast prefers to recall the affected lots entirely.

To implement this recall, please take the following actions:

1. Examine your inventory and quarantine the products affected by the recall.
2. Discontinue the use and distribution of the identified batch numbers.
3. In case You have already distributed some of the affected products, please identify Your customers and notify them of this product recall.
4. A credit note will be issued covering the cost of the recalled products.

This recall should be carried out to the final customer level.

Your assistance is appreciated. Diffuplast apologizes for any inconvenience this recall may cause You.

If You have any questions, please don't hesitate to contact us.

Yours faithfully,

Giuseppe Vignati
Diffuplast S.r.l