



URGENT: RECALL of LiNA Librata, endometrial ablation device

Customers of the LiNA Librata, endometrial ablation device

Glostrup, October 06, 2017

Dear Sir/ Madam,

Since we have observed glycerin leaking from Librata devices during the sterilization process we are unfortunately forced to withdraw all Librata's produced from week 25 to 28 in 2017 from the marked. Lot numbers as follow:

1725009
1725015
1725020
1726001
1726007
1726014
1726018
1727021
1727031
1728004
1728011
1728018
1728024
1728030
1728050

We are sorry about the inconvenience this may cause you.

To acknowledge receipt of this letter please complete the enclosed form (Exhibit A) with the number of devices that you have on stock in your inventory and those units that are located at the customer location/ in the possession of sales representatives.

Finally please indicate how many and which lot numbers have been used out and disposed of by the customers.

LiNA Medical ApS apologies for all inconvenience.

A handwritten signature in black ink, appearing to read "Anne Klitgård". The signature is written over a horizontal dotted line.

Anne Klitgård
VP QA RA Manager



EXHIBIT A: Acknowledgement Form

Customers of the LiNA Librata, endometrial ablation device

Glostrup, October 06, 2017

We hereby confirm to having received LiNA Medical ApS' letter of October 06, 2017 regarding the return of specific LiNA Librata products.

- We did not have any LiNA Librata products with the specified lot numbers.
- We have returned the following reference number:..... lot number:.....and quantity:.....of the enumerated by LiNA Medical Aps products. Details stated below:

Reconciliation, lot numbers and no of units :

inventory : _____

customer locations: _____

possession of sales representatives: _____

disposed of: _____

Acknowledged by:

Date: _____

Name & Title: _____

Signature: _____