



**URGENT: RECALL** of LiNA Gold Loop.

Customers of the LiNA Gold Loop device,

Glostrup, October 31, 2017

Dear Sir/ Madam,

Since we have received complaints regarding LiNA Gold Loop functionality problems related with self-activation of the devices. LiNA Medical ApS decided to perform recall of the below mentioned references and lot numbers.

Item number	lot number
EL-160-4	1646039
EL-200-4	1647045
EL-240-4	1650042
EL-200-4	1649037
EL-160-4	1648080
EL-200-4	1651056
EL-160-4	1652015
EL-160-4	1702068
EL-200-4	1703026
EL-200-4	1704904
EL-240-4	1706007
EL-160-4	1706061
EL-160-4	1710038
EL-200-4	1712002
EL-160-4	1710057
EL-160-4	1713018
EL-200-4	1714033
EL-160-4	1718905
EL-240-4	1718046
EL-160-4	1721038
EL-160-4	1734008
EL-200-4	1738057
EL-160-4	1741018

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 blue ink, appearing to read "Anne Klitgård", written over a dotted horizontal line.

Anne Klitgård  
VP QA RA Manager



## EXHIBIT A: Acknowledgement Form

Customers of the LiNA Gold Loop,

Glostrup, October 31, 2017

We hereby confirm to having received LiNA Medical ApS' letter of October 31, 2017 regarding the return of specific LiNA Gold Loop products.

- We did not have any LiNA Gold Loop 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: \_\_\_\_\_