September 16, 2019

Customer Information:
Customer Name
Address

Dear [Name],

Urgent:
Voluntary Recall of Recently Serviced Hearing Aids
Field Safety Notice- ID#MS0028308 v1

The safety and comfort of users is always our highest priority. We know that the safety and comfort of your customers is also yours.

This is to inform you of a voluntary product recall involving:

- Selected Behind-the-Ear hearing aids serviced by GN Hearing between August 14 and September 5, 2019 (see attached “Acknowledgement and Return Response Form” for a complete list of affected serial numbers)
- Selected In-the-Ear hearing aids serviced by GN Hearing between August 14 and September 5, 2019 (see attached “Acknowledgement and Return Response Form” for a complete list of affected serial numbers)

What is the Problem and Who is at Risk? GN Hearing received reports from our manufacturing site in US regarding a software bug in our service & repair tool which affected the capture and restoration of user data in a limited number of repaired hearing aids. The software bug caused these repaired hearing aids to contain altered specifications for sound amplification, potentially putting users’ residual hearing at risk of experiencing unintended additional available gain to varying degrees i.a.18dB flat linear gain or potentially in worst case Full On Gain. However, no injuries have been reported.

GN Hearing determined 2193 affected devices and is immediately initiating a removal of affected Behind-the-Ear (BTE) and In-the-Ear hearing aids, which were serviced between August 14 and September 5, 2019.

Our Service & Repair process has been updated to correct the software bug. GN Hearing wants to remove and repair all affected hearing aids and solve the issue in the fastest way possible. Therefore, we ask you to immediately do the following:

How to Identify the Affected Hearing Aids? We have identified all the affected hearing aids by serial number on the attached “Acknowledgment and Return Response” form.

Action to be taken by the customer/user
In order to correct or replace the affected hearing aids, we kindly ask you to perform the following:

For Behind-the-Ear (BTE) hearing aids:

1. Review your stock to determine if any of the affected hearing aids are still in your inventory. If so, please immediately quarantine the affected hearing aids and contact your local GN Hearing Sales company which will help you to return and replace the affected hearing aids. Replacement products will be sent to you as a top priority.
2. Determine whether any of the affected hearing aids have been delivered to your customers. If so, please contact the relevant customers immediately and ask them to cease using their hearing aids and bring them to your clinic for a free-of-charge replacement, if possible. Please keep records of calls and mails to and from customers. Returned hearing aids must be sent to your local GN Hearing Sales company, and replacement products will be sent to you as a top priority.

For In-the-Ear hearing aids:

1. Review your stock to determine if any of the affected hearing aids are in your inventory. If so, please immediately quarantine the affected hearing aids and contact your local GN Hearing Sales company which will help you to return and repair the affected hearing aids. The repaired hearing aids will be returned to you as a top priority.
2. Determine whether any of the affected hearing aids have been delivered to your customers. If so, please contact the relevant customers immediately and ask them to cease using their hearing aids and bring them to your clinic for a free-of-charge repair. Please keep records of calls and mails to and from customers. Returned hearing aids must be sent to your local GN Hearing Sales company for update. The updated hearing aids will be sent to you as a top priority.

Please fill out the “Acknowledgment and Return Response” form and immediately return the completed form to your local GN Hearing Sales company.

It is important that you pass this information on to all relevant organizations and individuals who need to be made aware of this urgent situation, so they can ensure appropriate action.
In line with standard procedures for Medical Device reporting, we will inform relevant regulatory authorities.

If you have any further questions or concerns, please contact the local GN Hearing Sales company

We sincerely apologize for the situation and be assured that we are working hard to minimize the inconvenience for you and your customers.

Best regards,

Signature
[Insert name , title and contact details]