

March 15, 2019

Notice of Voluntary Recall

Sivantos K.K.

7-10-1 Chuorinkan

Yamato-shi, Kanagawa

Dear vendors,

Thank you very much for your continued patronage.

We have discovered that the legally required labels printed on the outer boxes of our Dejimimi 3 medical devices are incorrect. We have decided to voluntarily recall the products to correct the problem.

If you are in possession of recalled products (please review "How to recognize products subject to the voluntary recall"), please cease selling/shipping them to purchasers and return them to the below address. Please also return the completed "Confirmation of recall of Dejimimi 3" to arrange priority delivery of substitute products to address the recall-related shortfall.

Please inform us of customers to whom you have sold and shipped voluntarily recalled products and allow us to contact them directly. We will then provide them with information on the voluntary recall and product return methods, etc. If you are unable to provide us with customer information and/or to allow us to contact customers directly, we regret to inform you that you will need to contact the customers yourselves. Please refer to the attached document entitled, "Information on voluntary recall for Dejimimi 3 purchasers," for details. We appreciate your cooperation.

Please note that these medical devices have no efficiency or safety-related issues and pose no risk to the health of purchasers. We sincerely apologize for any concerns or inconvenience caused to our vendors and to purchasers of our products and would greatly appreciate your understanding and cooperation with the recall process.

1. Product name

Dejimimi 3 in-the-ear hearing aids

2. Product number

Please refer to the list of voluntarily recalled products.

3. Packaging

Individually packaged

Return address:

Sivantos K.K.

Customer Service Department

Sanki Yamato Building 6F

7-10-1 Chuorinkan

Yamato-shi, Kanagawa 242-0007

Contact information :

Customer Service Department 0800-222-4133

Quality and Regulatory Affairs Department 046-407-6215

Dejimimi 3 How to identify product numbers

Product numbers can be found on the hearing aids themselves and on their outer boxes.

① Hearing aids



Product numbers are imprinted on the devices.



② Outer boxes



Product numbers are printed on labels affixed to the right side of boxes.

