

Sivantos GmbH · Henri-Dunant-Strasse 100 · D-91058 Erlangen

To Whom it May Concern

February 22, 2018

Rationale for an exemption from FCC-Labeling on the products of Nx platform

Ladies and Gentlemen,

following the advises in the reply of the inquiry to FCC (Tracking Number 560209, attachment A), find here the summary why we come to the conclusion that printing the Certification Identifier directly on the small hearing aids products of Nx platform is not possible with readable font size (e.g. 4-6 points equal to height 1.4 – 2.1mm).

The rationale is, that our hearing aids products of Nx platform are too small to reasonably apply any marking beyond the absolute minimum. Please refer to the photographs (attachment B), that show three of the most recent products (including largest) placed on paper with a millimeter grid. The devices are about 3.5 cm or less long. The surface is very curvy so there are only few parts that are suitable for printed information. We always try to leave the upper part of the shell unprinted, as it could be seen from outside and hearing aids should be almost imperceptible with the upper shell colour adapted to the patient's hair colour.

For readability reasons we do not print any other information, like FCC- and ISCED- identification numbers on the product itself but only in the user manual (see attachment C).

Thank you very much for your assistance in this matter. I hope the information is conclusive. Please do not hesitate to contact me if you have questions.

Sincerely,



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From: oetech@fcc.gov
Sent: 21 February 2018 15:06
To: Schaetzle, Uli
Subject: Response to Inquiry to FCC (Tracking Number 560209)

Inquiry on 02/16/2018 :

Inquiry:

Dear Sirs,

with update 82 FR 50826, Nov. 2, 2017 of the FCC equipment authorization procedures eCFR §2.925 "Identification of equipment" new rules to print the FCC Identifier on devices apply. For the nature of hearing aids to be very small, we face huge problems to print the FCC Identifier on our hearing aids. Though it may technically be possible to print it in a very small font that is four-point on hearing aids that are larger than 3cm we think this is very problematic for the majority of our hearing aids that are smaller and have a very uneven surface, difficult to print on. They are designed to be invisible inside the ear canal or to be small enough to hide behind the ear. Up to now we print on the shell the brand name "SIGNIA" or "SIEMENS" and the model name (e.g. "Motion 13 BT"), on the battery door the marking "CE0123" and inside the battery compartment the serial number. Any other information we do not print on the hearing aid itself but in the user manual.

Hoping for your understanding we apply for an exemption from labeling the FCC Identifier directly our hearing aids but print the information inside the user manual.

Thank you very much for your assistance in this matter. Do not hesitate to contact me if you have questions or need further information.

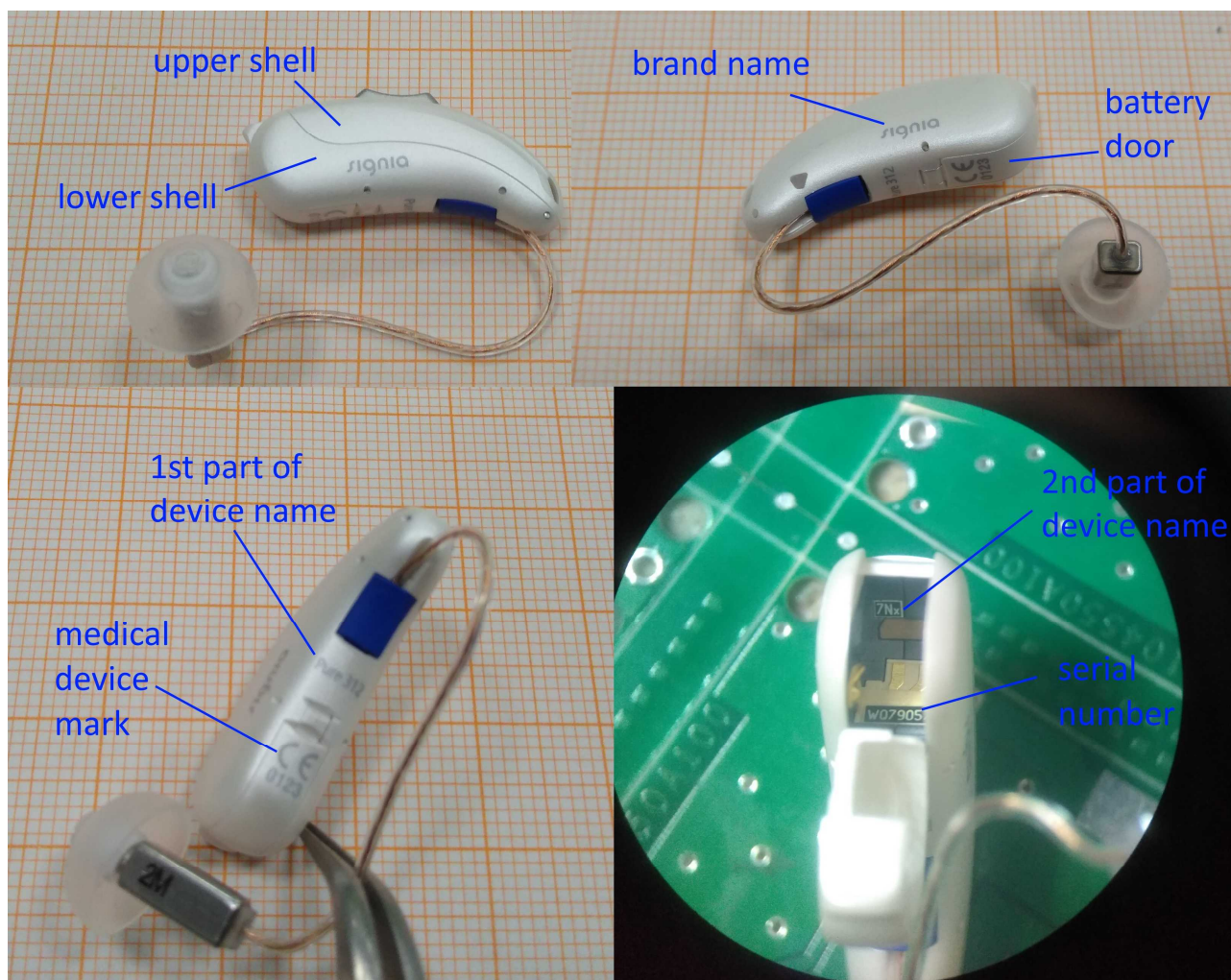
With best regards,
Ulrich Schaetzle

FCC response on 02/21/2018

If the device is unquestionably too small for the FCC ID to be readable (smaller than 4-6 points), the FCC ID may be placed in the user manual. However, it must be determined that the device itself is too small – the label area allocated to the FCC ID may not be reduced because of overcrowded identification of other product and regulatory information.

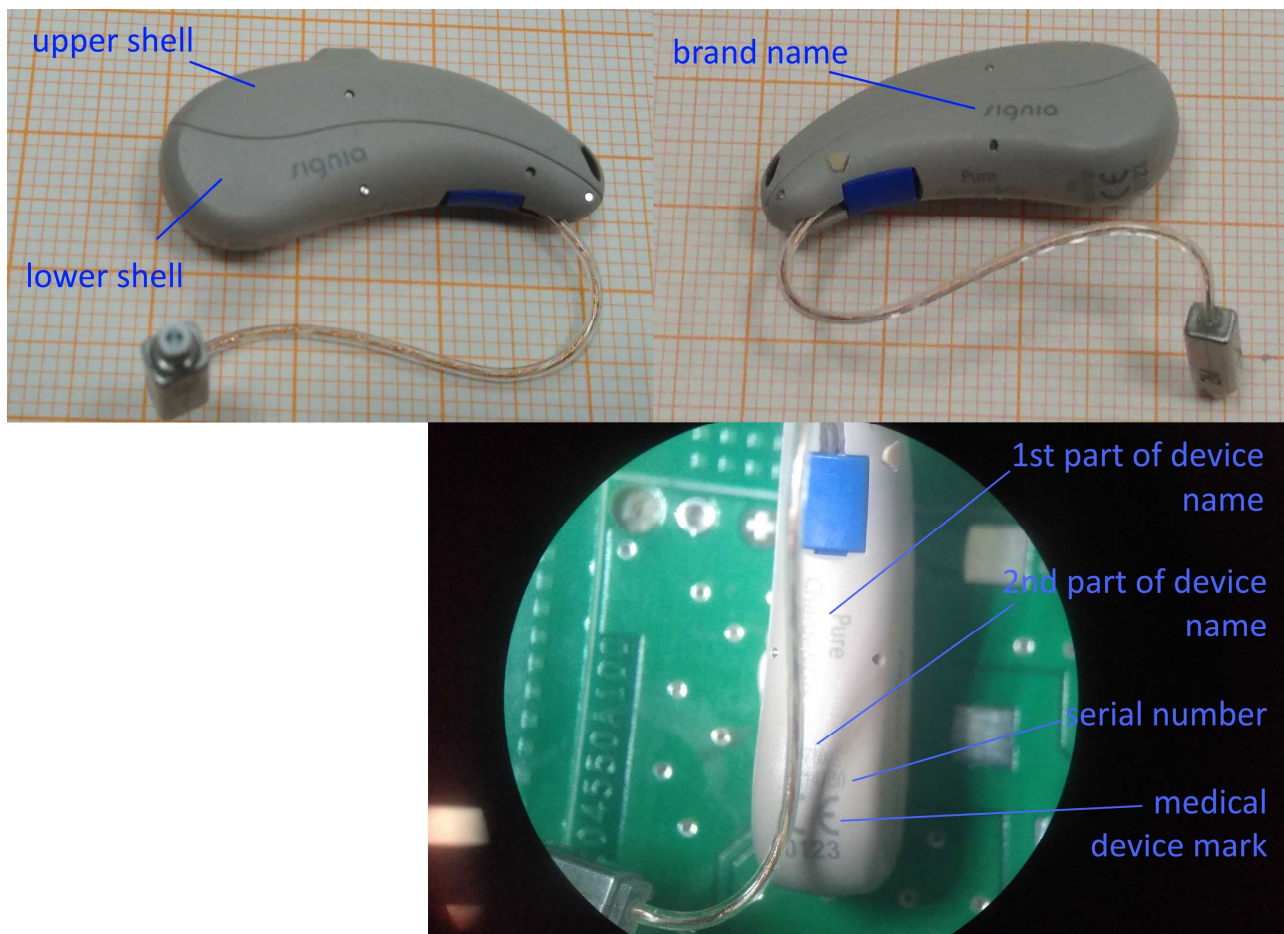
The following information can be obtained from our website at

<https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?switch=P&id=27980>. If the device meets the requirement then it is allowed. Also, labelling guidelines can be found in Knowledge DataBase (KDB) Publication [#784748](#)



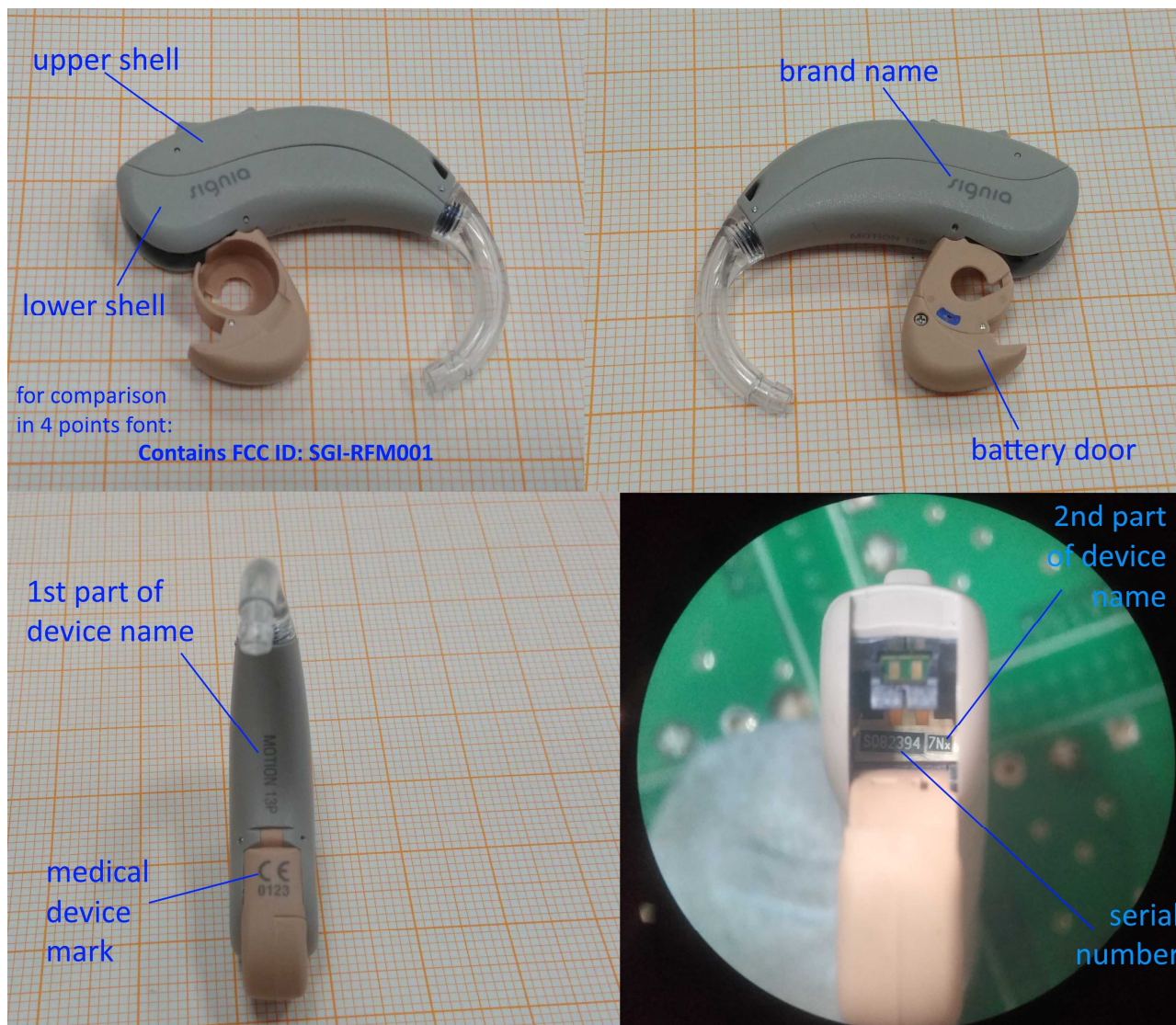
Picture 1: SIGNIA-brand hearing aid “Pure 312 7Nx”

On the lower part of the shell we do print our brand name “SIGNIA” as well as the 1st part of the model name “Pure 312” in small 1mm, equal to a 3-point font size. The mandatory marking for medical products “CE0123” is printed on the battery door as it is always same and battery doors can be used for different devices. The serial number “WQ79057” and the 2nd part of the model name “7Nx” are normally found inside the battery compartment printed in 0.7 mm font size, equal to an extremely small 2-point font (both only readable with a microscope).



Picture 2: SIGNIA-brand hearing aid “Pure Charge&Go 7Nx” (rechargeable instrument)

On the lower part of the shell we do print our brand name “SIGNIA” as well as the 1st part of the model name “Pure Charge&Go” in small 1mm height, equal to a 3-point font size. The mandatory marking for medical products “CE0123” is printed on battery area. As the Pure Charge&Go doesn’t have a battery door, it’s serial number “VQ14760” and rest of model name “7Nx” is printed above the CE-mark in 0.7 mm height, equal to an extremely small 2-point font size (again only readable with a microscope).



Picture 3: SIGNIA-brand hearing aid “Motion 13P 7Nx”

This is the largest hearing aid of the Nx platform. On the lower part of the shell we do print our brand name “SIGNIA” as well as the 1st part of the model name “Motion 13P” in small 1mm, equal to a 3-point font size. The mandatory marking for medical products “CE0123” is printed on the battery door as it is always same and battery doors can be used for different devices. The serial number “SQ82394” and the 2nd part of the model name “7Nx” are found inside the battery compartment printed in 0.7 mm font size, equal to an extremely small 2-point font (only readable with a microscope).

For comparison the FCC label in small 4 points font is shown in upper left picture to visualize that even with the largest hearing aid of the platform it is very problematic to find a suitable place for it.

Country-specific information

USA and Canada

Certification information for hearing instruments with wireless functionality:

Pure Charge&Go Nx

- Contains FCC ID: SGI-RFM001
- IC: 267AB-WP4N1

Picture 4: Snapshot from User Guide of Pure Charge&Go Nx hearing aid