

Note regarding labelling of the device INGENIA

Pursuant to paragraph §2.925 of 47 C.F.R. the Direct Acoustic Cochlear Implant System INGENIA (DACS PI), which is subject of this filing, shall bear a permanently affixed, readily visible label listing the information as specified in §2.926 and §15.19(a) of 47 C.F.R. Due to the specific use of the hearing instrument (as shown on Figure 1) its external surface is in a permanent contact with the skin behind the ear. Therefore, it is not appropriate to permanently affix a label on the outer surface of the device in order to prevent any possible skin irritations. In addition, the size of the FCC ID would be smaller than 2 points, which does not satisfy the requirements for “readily visible” label as defined in §2.925(d)(2) and §2.925(g).

Therefore, due to the very small size of the device and pursuant to paragraph §15.19(a)(5) of 47 C.F.R., the FCC ID and the statement specified in §15.19(a)(3) are placed in the user manual as shown on the next page.



Figure 1: Button Processor location on the head

8 INFORMATION AND EXPLANATION OF SYMBOLS

Notice

This device is certifies under:

Ingenia/DACS PI

FCC ID: X47 - DACSPI

IC: 8812°- DACSPI

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by Phonak may void the FCC authorization to operate this equipment.

Symbols



With this symbol, Phonak Acoustic Implant confirms that this product meets the requirements of the Medial Devices Directive 93/42/EEC as well as the Active Implanted Medical Devices 90/385/EEC. The numbers after the CE symbol correspond to the code of the certified institutions that were consulted under the above-mentioned directives.



This symbol indicated that the product described in this user guide adheres to the requirement for application of EN/IEC 60601-1 and EN 60601-1-2.



This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide.



This symbol indicates that it is important for the user to pay attention to the relevant warning notices in this user guide.