Classification of MD acc MDD 93/42/EEC Annex IX

1. Purpose

Generic classification document to classify hearing aids according the MDD 93/42/EEC.

2. Scope

Applies for hearing aids/hearing instruments, listed in the declarations of conformity of Phonak AG, Staefa: 000.000.006.013; 000.000.006.014.

3. Definition acc MDD 93/42/EEC Annex IX

BTE	Behind the ear *worn hearing aid*
RIC or CRT	Receiver in canal / canal receiver technology behind the ear *worn hearing aid, receiver in the canal*
ITE	In the ear worn *hearing aid*
ITC	In the canal worn *hearing aid*
CIC	Complete in canal *worn hearing aid*
MIC or	Micro in canal *worn hearing aid*
IIC	Invisible in canal *worn hearing aid*
MD	Medical Device
MDD	Medical Device Directive
SW	Software
MD classification	This document is a deliverable of the "Product Definition SOP" as design input document.
Accessory 93/42/EEC MDD Art.1 (b)	means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;
Intended Purpose 93/42/EEC MDD Art.1 (g)	means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;
Intended Use USA 21 CFR, Part 801.4	What you claim your device does [USA 21 CFR, Part 801 Labeling, Sec 801.4] (= European Intended Purpose)
Indication for Use USA 21 CFR, Part 814.20	Diseases, conditions, or pathologies you claim your device prevents, treats, cures, mitigates, or diagnoses (Indications). [USA 21 CFR, Part 814 Premarket approval of Medical devices, Sec 814.20 3(i)]
Medical Device 93/42/EEC MDD Art.1 (a)	means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - investigation, replacement or modification of the anatomy or of a physiological process, - control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;
Software as MD with a measuring function	may be subject to classification as a Class I medical device with a measuring function. Notified Body involvement is required for CE Marking.
Standalone Software	For the purpose of this guideline 'standalone software' means software which is not incorporated in a medical device at the time of its placing on the market or its making available.