audifon
hearing systems

Declaration of Conformity

Valid from: 21.02.2017
Valid until: 20.02.2022

Manufacturer: audifon GmbH & Co. KG
Address: Werner-von-Siemens-Straße 2
D - 99625 Kölleda / Thür. / Germany

Phone: +49-3635-4056-590
Fax: +49-3635-4056-589

Products / accessories:

Device name	Item number	Date of first marking
kami P	023170	21.03.2016
kami S	023168	21.03.2016
kami XS	023169	21.03.2016
kami R HE S	023171, 021952	21.03.2016
kami R HE M	023171, 021958	21.03.2016
kami P	023170	21.03.2016
sino P	023166	21.03.2016
sino S	023164	21.03.2016
sino XS	023165	21.03.2016
sino R HE S	023167, 021952	21.03.2016
sino R HE M	023167, 021958	21.03.2016
rega P	023174	21.03.2016
rega S	023172	21.03.2016
rega XS	023173	21.03.2016
rega R HE S	023175, 021952	21.03.2016
rega R HE M	023175, 021958	21.03.2016

Part 1:
We declare under our sole responsibility that the above-mentioned products comply with the following directives:

Medical Device Directive (MDD) 93/42 EEC, appendix I
Medical Device Directive 2007/47/EEC

The above-mentioned hearing aids are classified in the category IIa and they are marked with

CE 0297

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Our company is certified according to DIN EN ISO 13485 and fulfils the relevant directives 93/42/EWG, appendix II part 3.

The conformity of the Medical Device Directive is certified by DQS Medizinprodukte GmbH (NB 0297).

DQS Medizinprodukte GmbH
August Schanz Straße 21
60433 Frankfurt am Main

Part 2:
We declare under our sole responsibility that the above-mentioned products / accessories comply with the following directives:

RoHS Directive 2011/65/EG

Kölleda, 16.02.2017

Ingo Henze
Qualitymanager

Kölleda, 16.02.2017

Anne Raber
Regulatory Affairs