

Declaration of Conformity

Valid from: 21.12.2019
Valid until: 26.05.2024

Manufacturer: audifon GmbH & Co. KG
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Products / accessories:

Device name	Item number	Date of first marking
rega pico	023303	17.10.2016
rega CIC	023305	17.10.2016
rega ITE	023307	17.10.2016
kami CIC	023299	17.10.2016
kami ITE	023301	17.10.2016
sino CIC	023295	17.10.2016
sino ITE	023298	17.10.2016

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.

Our company is certified according to DIN EN ISO 13485 and fulfils the relevant directives 93/42/EEG, 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, 21.12.2019



Joerg Hensel, CEO