

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 |
|-------------|-------------|-----------------------|
| 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/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