audifon
hearing systems

# Declaration of Conformity

Valid from: 05.10.2017
Valid until: 20.02.2022

Manufacturer: audifon GmbH & Co. KG
Address: Werner-von-Siemens-Straße 2
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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/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

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**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, 05.10.2017

Ingo Henze
Qualitymanager

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Kölleda, 05.10.2017

Anne Raber
Regulatory Affairs