

Declaration of Conformity

Valid from: 29.08.2019
Valid until: 20.02.2023

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

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Products:

Device name	Item number	Date of first marking
lewi S	029808	29.08.2019
lewi R	029809	29.08.2019
risa S	030239	29.08.2019
risa R	030240	29.08.2019

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



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:

Radio Equipment Directive 2014/53/EU

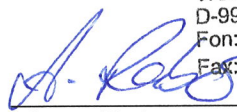
Part 3:

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

RoHS Directive 2011/65/EG

Kölleda, 17.12.2021

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