

Declaration of Conformity

Valid from:

24.08.2020

Valid until:

26.05.2024

Manufacturer:

audifon GmbH & Co. KG

Address:

Werner-von-Siemens-Straße 2

D - 99625 Kölleda / Thuringia / Germany

Phone:

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Products:

Device name	ltem number	Date of first marking
sueno pro R	025381	18.09.2017
sueno pro ITE	025383	18.09.2017
sueno pro S	031625	24.08.2020

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

C€0297

Our company is certified according to DIN EN ISO 13485 and fulfills 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, 19.08.2020

audifon GmbH & Co.KG Werner-von-Siemens-Strasse 2 D-99625 Kölleda/ Thür.

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Ingo Henze Quality Manager