

Declaration of Conformity

Valid from:

19.06.2020

Valid until:

26.05.2024

Manufacturer:

audifon GmbH & Co. KG

Address:

Werner-von-Siemens-Straße 2

D - 99625 Kölleda / Thuringia / Germany

Phone:

+49-3635-4056-590

Fax:

+49-3635-4056-589

Products / accessories:

Device name	Item number	Date of first marking
Audifit (Version 5.8)	021319	19.06.2020

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 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

audifon GmbH & Co.KG Werner-von-Siemens-Strasse 2 D-99625 Köllede/Think

D-99625 Kölleda/ Thür. Fon: +49(0)36 35-40 56 629 Fax: +49(0)36 35-40 56 529

Ingo Henze Qualitymanager

Kölleda, 15.06.2020