audifon
hearing systems

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 CE marking
audifon via pro S+ Rx	022529	10.03.2015
audifon via pro S+ Tx	022530	10.03.2015
audifon via pro P Rx	022534	10.03.2015
audifon via pro P Tx	022535	10.03.2015
audifon via pro R Rx, HE S	022539, 021957	10.03.2015
audifon via pro R Rx, HE M	022539, 021958	10.03.2015
audifon via pro R Tx, HE S	022540, 021957	10.03.2015

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

CE 0297

Our company is certified according to DIN EN ISO 13485 and fulfils the relevant directives 93/42/EWG, appendix II part 3.

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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
R&TTE Directive 1999/5/EG (For further particulars refer to appendix R&TTE)

Kölleda, 16.02.2017

Ingo Henze
Qualitymanager

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Appendix (R&TTE)
referring to Declaration of Conformity No. 702/06

Products / accessories:

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audifon via pro P Tx	022535	10.03.2015
audifon via pro R Rx, HE S	022539, 021957	10.03.2015
audifon via pro R Rx, HE M	022539, 021958	10.03.2015
audifon via pro R Tx, HE S	022540, 021957	10.03.2015

The above-mentioned product complies with the provisions of Directive 1999/5/EG and conforms with the following standards:

DIN EN 62479:2011, Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

DIN EN 60950-1:2011, Information technology equipment – Safety – Part 1: General requirements

ETSI EN 300 330-1 V1.7.1 (2010-02), Electromagnetic compatibility and radio spectrum Matters (ERM); Short Range Devices (SDR); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz;
Part 1: Technical characteristics and test methods.

ETSI EN 300 330-2 V1.5.1 (2010-02), Electromagnetic compatibility and radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz;
Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive.

ETSI EN 301 489-1 V1.8.1 (2008-04), Electromagnetic compatibility and radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

ETSI EN 301 489-3 V1.4.1 (2002-08), Electromagnetic compatibility and radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz.

Kölleda, 16.02.2017

Ingo Henze
Qualitymanager