

## 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 Köllda / Thür. / Germany

Phone: +49-3635-4056-590  
Fax: +49-3635-4056-589

### Products / accessories:

Device name	Item number	Date of first CE marking
audifon faro IS	022521	10.03.2015
audifon faro IS TRT	022523	10.03.2015
audifon faro IS+	022525	10.03.2015
audifon faro IS+ TRT	022527	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.

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

### **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)

Köllda, 16.02.2017



Ingo Henze  
Qualitymanager

**Appendix (R&TTE)  
referring to Declaration of Conformity No. 704/03**

**Products / accessories:**

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audifon faro IS	022521	10.03.2015
audifon faro IS TRT	022523	10.03.2015
audifon faro IS+	022525	10.03.2015
audifon faro IS+ TRT	022527	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