audifon
hearing systems

Declaration of Conformity

Amended: Kölleda, 15.05.2024
"Legacy Devices" and further placing on the market in accordance with Confirmation Letter EU 2023-607 of DQS Medizinprodukte GmbH
M. Rümke PRRC audifon GmbH & Co. KG (see „a19“, „a29“ and „a39“)

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

Products:

Device name	Item 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

CE 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

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Part 2:

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

RoHS Directive 2011/65/EG

audifon GmbH & Co.KG
Werner-von-Siemens-Strasse 2
D-99625 Kölleda/ Thür.
Fon: +49(0)36 35-40 56 629
Fax: +49(0)36 35-40 56 529

Kölleda, 19.08.2020

Ingo Henze
Quality Manager

audifon
hearing systems

The following table contains the assignment of the product names according to MDD declarations of conformity to the corresponding product names according to the Confirmation Letter of DQS Medizinprodukte-GmbH Reference Number: 1000178134

Product names according to MDR	Product names according to MDD
a10 /a19 and a20/ a29	Via pro S+Rx, Via pro S+Tx, Via pro P Rx, Via pro P Tx, Via pro R Rx, HE S, Via pro R Rx, HE M, Via pro R Tx, HE S, Via pro R Tx, HE M Sino P, Sino S, sino XS , sino R HE M, sino R HE S, kami P, kami S, kami XS, kami R HE S, kami R HE M, rega P, rega S, rega XS, rega R HE S, rega R HE M Vico M, vico M TRT, vico S, vico S TRT, vico XS, vico XS TRT, vico S+, vico S+ TRT, vico P, vico P TRT lewi S, lewi R, risa S, risa R sueno pro R, sueno pro S
a30/a39	via pro IS Rx, via pro IS Tx, via pro IS+ Rx, via pro IS+ Tx sueno pro ITE vico CIC, vico CIC P,vico CIC TRT, vico IS, vico IS P, vico IS TRT, vico IS+, vico IS+ P, vico IS+ TRT rega pico, rega CIC, rega ITE, kami CIC, kami ITE, sino CIC, sino ITE
a40	Receiver Unit S-HE S, Receiver Unit M-HE M, Receiver Unit P-HE P
a50	Tulpe, offen, power, Thin Tube,easyfit S, easyfit R
a60	audifit(version 5.8)
a70	audifon app(wings app)

Kölleda/Germany,21.11.2024

Jörg Hensel/ CEO

audifon GmbH & Co. KG
Werner-von-Siemens-Strasse 2
D-99625 Kölleda / Thür.
Fon: +49 (0)3635 - 40 56 590
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Kölleda/Germany,21.11.2024

Martin Rümke/ PRRC

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DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

audifon GmbH & Co. KG
Werner-von-Siemens-Str. 2
99625 Kölleda
Germany

Date: 2024-05-15

Notified Body Confirmation Letter
Reference: 1000178134

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

audifon GmbH & Co. KG
Werner-von-Siemens-Str. 2
99625 Kölleda
Germany

SRN: DE-MF-000008355

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices. The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Viviana Indraccolo
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
a70 ++EADFa707W	Class IIa	Hearing aid systems incl. hearing aid devices, software and accessories.	494148 MR2 170741417 (NB 0297)
a60 ++EADFa607T	Class IIa	Hearing aid systems incl. hearing aid devices, software and accessories.	494148 MR2 170741417 (NB 0297)
a50 ++EADFa50HNQA	Class IIa	Hearing aid systems incl. hearing aid devices, software and accessories.	494148 MR2 170741417 (NB 0297)
a10 ++EADFa10HNPE **a19** ++EADFa19NW2	Class IIa	Hearing aid systems incl. hearing aid devices, software and accessories.	494148 MR2 170741417 (NB 0297)
a40 ++EADFa40HNQ3	Class IIa	Hearing aid systems incl. hearing aid devices, software and accessories.	494148 MR2 170741417 (NB 0297)
a30 ++EADFa807Z **a39** ++EADFa39NWC	Class IIa	Hearing aid systems incl. hearing aid devices, software and accessories.	494148 MR2 170741417 (NB 0297)
a20 ++EADFa20HNPM **a29** ++EADFa29NW7	Class IIa	Hearing aid systems incl. hearing aid devices, software and accessories.	494148 MR2 170741417(NB 0297)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
N/A	N/A	Initial issue