EU Quality Management Certificate

This is to certify that the company

audifon GmbH & Co. KG

Werner-von-Siemens-Str. 2
99625 Kölleda
Germany

SRN: DE-MF-000008355

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	494148 MDR2017Q
Certificate ID	1000199393
Effective date	2024-09-30
Expiry date	2029-09-29
Frankfurt am Main,	2024-09-30

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000008355
Certificate ID: 1000199393

Device categories and variants covered by this certificate:

Device category:	**MDA 0310 - Active non-implantable devices for ear, nose and throat**
Product name:	a40
Risk classification:	IIa
Basic-UDI-DI:	++EADFa40HNQ3
Intended purpose:	Receiver units are an accessory for designated hearing aids and noiser and are intended to transform the electrical signal from the processor unit into an acoustical signal at the ear canal. The bending and lengths of the tubing ensures proper and secure placement of the system.

Device category:	**MDA 0310 - Active non-implantable devices for ear, nose and throat**
Product name:	a10, a20, a30
Risk classification:	IIa
Basic-UDI-DI:	++EADFa10HNPE, ++EADFa20HNPM, ++EADFa30HNPU
Intended purpose:	The intended purpose of hearing aids is to minimize the effects of the individual hearing loss as far as possible, by detecting and amplifying sound signals from the environment that are of interest for the patient and conducting them through air to the eardrum. While amplifying the sounds, the individual uncomfortable listing levels are also accounted for to reduce aggravation of hearing loss. The goal is to improve the speech intelligibility and listening effort for the patient in quiet and noisy environments. The noiser module is intended to be used as integral part of a tinnitus therapy protocol. In combination with other therapeutic measures, the noises produced by the noiser module are supposed to reduce the saliency of the tinnitus for the patient.

Device category:	**MDA 0310 - Active non-implantable devices for ear, nose and throat**
Product name:	a19, a29, a39
Risk classification:	IIa
Basic-UDI-DI:	++EADFa19NW2, ++EADFa29NW7, ++EADFa39NWC
Intended purpose:	The noiser module is intended to be used as integral part of a tinnitus therapy protocol. In combination with other therapeutic measures, the noisesproduced by the noiser module are supposed to reduce the saliency of the tinnitus for the patient.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000008355
Certificate ID: 1000199393

Examinations and tests performed:
494148_A209570MED_01 dated 2022-06-18
494148_A209570MED_a40 Höreinheit dated 2024-09-06

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a