

EU QUALITY ASSURANCE CERTIFICATE

Certificate no.
1379GB449250929

Final Assessment Report no.
1379AU28F

Effective date
2025-09-29

Expiry date
2029-09-23

This is to certify that the quality system of

Acousticon Hörsysteme GmbH

Hirschbachstraße 48, 64354 Reinheim, Germany

SRN: DE-MF-000013831

For manufacturing and final product inspection/testing of

Medical devices/groups of medical devices at locations as listed on the following pages

has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex XI, Part A
of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2025-09-29

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany



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

BS-MDR-096

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact medcert-info@dnv.com


Annika Chill
Certification Body Operations



DNV

Certificate no.: 1379GB449250929
Place and date: Hamburg, 2025-09-29

Sites covered by this certificate

Acousticon Hörsysteme GmbH, Hirschbachstraße 48, 64354 Reinheim, Germany

Preceding certificate

Certificate no.	Issue date	Identification of changes
N/A	N/A	N/A

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0204	Z121401	AUDIOMETERS

