EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

GN ReSound A/S

Lautrupbjerg 7
2750 Ballerup
Denmark

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Hearing instruments, Tinnitus Devices, Software, Ear moulds and Programming Interface according to the annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	099446 MR2
Certificate unique ID	170771083
Effective date	2020-08-06
Expiry date	2024-05-26
Frankfurt am Main	2020-08-06

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 099446 MR2
Certificate unique ID: 170771083
Effective date: 2020-08-06

GN ReSound A/S

Lautrupbjerg 7
2750 Ballerup
Denmark

Product Form Factor (PFF)	Type	Class
BE60 00	BTE	IIa
BE60 01	BTE	IIa
BE70 00	BTE	IIa
BE70 01	BTE	IIa
BE80 00	BTE	IIa
BE80 01	BTE	IIa
BEB60 02	BTE	IIa
BEB70 02	BTE	IIa
BEB80 02	BTE	IIa
BER13 02	BTE	IIa
BO10 00	FP/ITE	IIa
BO13 00	FP/ITE	IIa
BO312 00	FP/ITE	IIa
BRIE 00	BTE	IIa
BRIE 01	BTE	IIa
CAR12A 03	BTE	IIa
CAR13A 03	BTE	IIa
CAR46A 03	BTE	IIa
CCS 00	FP/ITE	IIa
CSI12 02	ITE	IIa
CSI13 02	ITE	IIa
CSX10 02	ITE	IIa
CSX12 02	ITE	IIa
CSX13 02	ITE	IIa
DA10 00	FP/ITE	IIa
DA10 01	FP/ITE	IIa
DA13i 00	FP/ITE	IIa
DA13i 01	FP/ITE	IIa
DA13r 00	FP/ITE	IIa
DA13r 01	FP/ITE	IIa
DA312i 00	FP/ITE	IIa
DA312i 01	FP/ITE	IIa
DA312r 00	FP/ITE	IIa
DA312r 01	FP/ITE	IIa
DE60 00	BTE	IIa
DE7080 00	BTE	IIa
DE90 00	BTE	IIa
LO85 00	BTE	IIa
LO90 00	BTE	IIa
LO90 01	BTE	IIa
LOB90 02	BTE	IIa
LXR45 02	BTE	IIa
M60 00	BTE	IIa
M7080 00	BTE	IIa
M7080E 00	BTE	IIa
MA70 00	BTE	IIa

This annex is only valid in connection with the above-mentioned certificate.

Annex to certificate
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GN ReSound A/S

Lautrupbjerg 7
2750 Ballerup
Denmark

Product Form Factor (PFF)	Type	Class
ME60 00	BTE	IIa
ME7080 00	BTE	IIa
MRIE 00	BTE	IIa
PA60 00	BTE	IIa
PA70 00	BTE	IIa
PA80 00	BTE	IIa
PH10 00	FP/ITE	IIa
PH13 00	FP/ITE	IIa
PH312 00	FP/ITE	IIa
Reno 00	FP/ITE	IIa
Shang 00	BTE	IIa
SY10 00	BTE	IIa
SY312 00	BTE	IIa
SY312E 00	BTE	IIa
VE312 00	BTE	IIa
VE312 01	BTE	IIa
VER12 02	BTE	IIa
Viking 00	BTE	IIa

Accessories		
Model	**Type**	**Class**
Amplifon Aventa	FSW	IIa
Amplifon Smart Fit	FSW	IIa
Aventa	FSW	IIa
Choice	App	IIa
Control	App	IIa
Costco Smart Fit	FSW	IIa
CS Smart Fit	FSW	IIa
Ear Mould	FP/ITE	IIa
Navigator	App	IIa
Smart	App	IIa
Smart 3D	App	IIa
Smart Fit	FSW	IIa
Smart Fit Ltd	FSW	IIa
SpeedLink	Programming Interface	IIa

This annex is only valid in connection with the above-mentioned certificate.

CERTIFICATE

This is to certify that the company

GN ReSound A/S

Lautrupbjerg 7
2750 Ballerup
Denmark

has implemented and maintains a **Quality Management System**.

Scope:
Design and development, manufacturing, service and repair of hearing instruments, components for hearing instruments, tinnitus maskers, remote controls, programming interfaces, accessories and spare parts.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	099446 MP2016
Certificate unique ID	170762879
Effective date	2021-01-01
Expiry date	2023-12-31
Frankfurt am Main	2020-12-28

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

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