CONFIRMATION OF CERTIFICATION

Frankfurt a. M.,
2015-09-08

To whom it may concern,

DQS Medizinprodukte GmbH hereby confirms that the company:

GN ReSound A/S
Lautrupbjerg 7
(P.O. Box 130)
2750 Ballerup
Denmark

has implemented and maintains a Quality Management System that conforms to EN ISO 13485:2012 + AC: 2012 . The current certificate has the registration number of 099446 MP2012, and the unique ID number of 170587107. The certificate was issued on 2015-01-01 and is valid until 2017-12-31.

Therefore, it is confirmed that the products shown on the certificate with the registration number of 099446 MR2, and the unique ID 170616781 (issued on 2015-03-02 and valid until 2019-12-31), have been designed and manufactured within a Quality Assurance System that fulfils the requirements of MDD 93/42/EEC and can be placed on the market within the European Union bearing CE-0297 under the responsibility of GN Resound A/S.

This document certifies that the below mentioned models may be placed on the market in the EU.

The manufacturing plant in which the devices are produced is subject to periodic inspections.

August-Schanz-Straße 21
60433 Frankfurt a.M.
Deutschland

Tel. +49 69 95427-300
Fax +49 69 95427-388
www.dqs-med.de
info@dqs-med.de

Geschäftsführer:
Frank Graichen

Sitz: Frankfurt am Main
Amtsgericht HRB 83350
Ust-IdNr. DE 260 263 917
Steuer-Nr. 045 231 74323

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

GN ReSound A/S

Lautrupbjerg 7
(P.O. Box 130)
2750 Ballerup
Denmark

also Trading as

ReSound A/S

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	170616781
Effective date	2015-03-02
Expiry date	2019-12-31
Frankfurt am Main	2015-03-02

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

20120803/2/EN380308

CERTIFICATE

This is to certify that the company

GN ReSound A/S

Head Office

Lautrupbjerg 7
(P.O. Box 130)
2750 Ballerup
Denmark

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

Scope:
Design, manufacturing, service and repair of hearing instruments, tinnitus maskers, remote controls, programming interface, 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:

ISO 13485 : 2003

Certificate registration no.	099446 MP23CMDR
Certificate unique ID	170587074
Effective date	2015-01-01
Expiry date	2017-12-31
Frankfurt am Main	2014-12-11

SCC Accredited CB-MS OCSM Accrédité CCN

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Maxim Shkolnikov
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de

DQS Medizinprodukte GmbH is a CMDCAS recognized registrar (Canadian Medical Devices Conformity Assessment System).

20111215/I/EN380313