Quality System Certificate

Number

DGM-016 with Attachment 1

This is to certify that the quality system of

Interacoustics A/S

Drejervænget 8, 5610 Assens
Denmark

has been approved in conformity with the requirements of Annex VI Section 3.2 (Product quality assurance) of Council Directive 93/42/EEC concerning medical devices

The scope of the certification is the following:

Manufacture and distribution of Audiometers and Hearing Aid Analyzers in class IIa

The Quality System Certificate is valid for one year from the date of issue given below. After this, the Quality System Certificate is valid for one year from the latest surveillance audit carried out with a satisfactory result, provided that documentation to substantiate validity is given in the form of an Annex A to the Certificate, and provided that the company does not introduce substantial changes to the quality system without the approval of DGM. Surveillance audit will be carried out annually by DGM. The Quality System Certificate is issued pursuant to the DGM Rules for the Certification of Medical Devices in order to affix the CE mark.

Date of issue: 1996-08-14

Poul Schmidt-Andersen
Director, DGM Verifier

Steffen Strøbæk
Lead Auditor

Danish Medical Devices Certification
Notified Body, Identification No. 0543
Kollegievej 6, DK-2920 Charlottenlund, Denmark

EC Certificate

Number

DGM-016 with attachment 1

This is to certify that the quality system of

Interacoustics A/S
Drejervænget 8, 5610 Assens
Denmark

has been approved in conformity with the requirements of

Annex VI Section 3.2 - Product quality assurance

of Council Directive 93/42/EEC concerning medical devices

The scope of the certification is:

Final inspection, test and distribution of Stationary Hearing Aids, Audiometers and Hearing Aid Analysers in class IIa

The EC Certificate is valid for one year from the date of issue given below.
After this date the EC Certificate is valid for one year from the latest surveillance audit carried out with a satisfactory result, provided that documentation to substantiate validity is given in the form of an Annex A to the Certificate, and provided that the company does not introduce substantial changes to the quality system without the approval of DGM. The EC Certificate is issued pursuant to the DGM Rules for the Certification of Medical Devices in order to affix the CE mark. The agreed number of surveillance audits after date of issue is one per year.

Poul Schmidt-Andersen
Director, DGM Verifier

1997-05-13
Revision date

1996-09-02
Date of issue

Søren Lindskov Hansen
Lead Auditor

Danish Medical Devices Certification
Notified Body, Identification No. 0543
Kollegievej 6, 2920 Charlottenlund, Denmark

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