

EC Declaration of Conformity

Product:

Product type: Accessory - Eartip

Trademark: Sanibel

Type No.: Various

Serial Numbers: N/A

Manufacturer:

Name: **Sanibel Supply A/S**

Address: **Audiometer Allé 1**

Area code/Area: **5500 Middelfart**

Phone No.: **(+45) 63713555**

Country: **Denmark**

Fax No.: **(+45) 63713522**

According to Annex VII of the Council Directive 93/42/EEC of 14 June 1993, including all amendments, concerning medical devices, we declare the Class I product above is fulfilling the essential requirements in appendix I of the Directive.

The conformity is achieved by the fulfilling of the following main standards:

- ISO 10993-1

This declaration is made on the sole responsibility of:

Company: **Sanibel Supply A/S**

Address: **Audiometer Allé 1**

Area code/Area: **5500 Middelfart**

Phone No.: **(+45) 63713555**

Country: **Denmark**

Fax No.: **(+45) 63713522**

Signature: 

Name: **Erik Nielsen**

Title: **Director, Quality & Regulatory Affairs**

Date: **2016-04-29**
(YYYY-MM-DD)