

EU Declaration of Conformity

Manufacturer:



Etymonic Design Incorporated
(operating as Audioscan)
20 Ludwig Street
Dorchester, Ontario,
CANADA, N0L 1G4

**European Authorized
Representative:**



Medical Device Safety Service
Schiffgraben 41
30175 Hannover, Germany

CE-marked Products:

Audioscan Model Verifit VF-2, Hearing Instrument Fitting System
Audioscan Model Axiom, Hearing Instrument Fitting System
Audioscan Model RM500SL, Hearing Instrument Fitting System
Audioscan Model Verifit VF-1, Hearing Instrument Fitting System

Products Classification:

Class IIa medical devices as defined by European Medical Devices Directive 93/42/EEC


Declaration:

We, the manufacturer, hereby declare and ensure with sole responsibility, that the above mentioned Medical Devices meet the provisions of Council Directive 93/42/EEC (Medical Device Directive) which apply to them.

The obligations laid down in Annex V are fulfilled with a quality system approved for the manufacture of the products via certification issued by BSI, ID #0086, certificate# CE 543241

Date of Validity:

November 29, 2016

D. B. Whitred 
Regulatory Affairs Manager,
Quality System Management Representative