

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 543241
Issued To: **Etymonic Design Inc.**
operating as audioscan
20 Ludwig St.
Dorchester
Ontario
N0L 1G4
Canada

In respect of:

Manufacture of hearing instrument fitting systems and accessories used for testing hearing aids.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Gary Fenton, Global Assurance Director

First Issued: **27 May 2009**

Date: **16 May 2014**

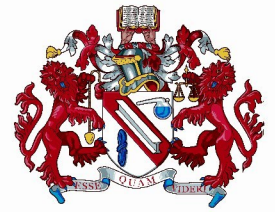
Expiry Date: **26 May 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

PC Werth
Audiology House
45 Nightingale Lane
London
SW12 8SP
United Kingdom

Service(s) supplied

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

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 Ontario
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 Canada**

Date	Reference Number	Action
27 May 2009	7286191	First Issue
30 March 2012	7807449	Certificate reissue due to change of company address from "41 Byron Ave, Dorchester N0L 1G0" to "20 Ludwig St., Dorchester N0L 1G4"
16 May 2014	8108741	Certificate renewal

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