

QUALITY SYSTEM

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# EC-CERTIFICATE

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## Directive 93/42/EEC

Manufacturer: Tondi Electronics Ltd  
Pärnu mnt 142  
11317 Tallinn, Estonia

Coverage of Certificate: Final inspection

Product category: Hearing aids

Valid until: 26th April 2015

The manufacturer's quality system for the final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex VI Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex VI in Directive 93/42/EEC. This Certificate is based on decision no. VTT-C-5340-01-1090-381-10-P0.

Tampere, 26<sup>th</sup> April 2010





Kaarle Kylmä



Seppo Lavonen

Certificate no.  
VTT-C-5340-01-1090-381-10

Notified Body no. 0537:  
VTT Expert Services Ltd.  
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## DECISION

on a quality system and product range covered, based on Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Annex VI Section 3.

Decision no.:	<b>VTT-C-5340-01-1090-381-10-P0</b>
Manufacturer:	Tondi Electronics Ltd. Pärnu mnt 142, 11317 Tallinn Estonia
Date of application:	30.3.2010
Activity and product category:	Final inspection, Hearing aids, class IIa.
Decision:	A certificate will be issued for the manufacturer. The certificate covers the following products: Hearing aids, risk class IIa, covering the following model range: U-2M1, U-2M4, U-2M6, U-03M, KA-03, KA-03A, KA-03B, KA-04, KA-04A, KA-04B, KA-05, KA-06, KA-07, KA-08, KA-11, KA-12, KA-13, KA-14, KA-15, KA-17, KA-54, KA-56.
Justification:	The manufacturer's quality system has been assessed and VTT Expert Services Ltd has found that the quality system and the products meet the requirements of Annex VI of Medical Device Directive 93/42/EEC in final inspection. The decision is based on change assessment report NB-1090-M2 and on audit report no. NB-1090-A7. The company has signed the undertaking to follow the obligations of Annex VI of the Directive.
Certificate related to decision:	VTT-C-5340-01-1090-381-10
Valid until:	This decision is valid until 26 <sup>th</sup> April 2015 unless the validity of the related certificate is changed.
Date:	Tampere, 26th April 2010



  
Kaarle Kylmä

  
Seppo Lavonen

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.

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