

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 01505****Issued To:**

**Starkey Laboratories, Inc**  
**doing business as Starkey Hearing**  
**Technologies under the brand names**  
**Starkey, Paradigm, Audibel, AudioSync**  
**Audika, VISAUDIO, ProAkustik, Silvertone,**  
**NuEar and MicroTech**  
**6600 Washington Ave South, Eden Prairie**  
**Minnesota**  
**55344**  
**USA**

**In respect of:**

**The design and manufacture of: in-the-ear hearing aids intended to be programmed and adapted for individual use; analogue, programmable and digital behind the ear hearing aids; hearing aid programming systems; sound generators.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 December 1996**

Date: **30 November 2016**

Expiry Date: **22 December 2021**

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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:	Service(s) supplied
Intricon Pte.Ltd. No. 8 Admiralty Street #02-01 to 06 Admirax 757438 Singapore	Manufacture
Starkey (Suzhou) Hearing Technology Co., Ltd. No, 1 Bin Te Li Road Suzhou Industrial Park Suzhou Jiangsu 215021 China	Manufacture
Starkey France S.A.R.L. 23 Rue Claude Nicolas Ledoux Europarc Batiment 14 94000 Creteil France	Manufacture Packaging

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Subcontractor:	Service(s) supplied
Starkey Italy S.r.l. via Torino, 51 Cernusco Sul Naviglio Milan 20063 Italy	Manufacture Packaging
Starkey Laboratories Inc 2915 10th Street East Glencoe Minnesota 55336 USA	Manufacture
Starkey Laboratories Ltd William F Austin House Bramhall Technology Park Hazel Grove Stockport SK7 5BX United Kingdom	EU Representative Final Manufacture Packaging

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### Subcontractor:

### Service(s) supplied

Starkey Mexico S.A de CV  
 Calle Norte 7 Lote 2 y 3  
 Entre Diagonal Lorenzo  
 de La Garza Y Peniente 2  
 Colonia Ciudad Intustrial  
 H. Matamoros  
 Tamaulipas  
 CP 87499  
 Mexico

**Manufacture**

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Date	Reference Number	Action
23 December 1996		First issued
16 October 1997		Change of scope
20 January 1999		Change of scope Addition of subcontractors
31 August 1999		Change of scope Addition of subcontractors
28 June 2001		Change of company name
29 May 2002		Change of scope Change to subcontractor activities
14 May 2003		Change of scope
17 May 2004		Change of scope Addition of subcontractors Certificate renewal

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Date	Reference Number	Action
03 February 2005		Change of subcontractors list due to addition of two new subcontractors in Canada and Australia. In addition, corrections to addresses for the following subcontract manufacturers of hearing aids: Starkey Italy S.r.l, Milano and Audiotechnica di Lo Coco Luigi S.n.c., Palermo
15 June 2005		Change of scope to add "sound generators" Change of subcontractors list due to addition of Micro-Tech Hearing Instruments
15 December 2006		Changes to subcontractors list: change of address for Starkey Laboratories (Germany) GmbH and Starkey Laboratorium Kft (Hungary), removal of Starkey Switzerland S.A. AV, removal of Starkey Benelux and removal of 'Design' from service supplied by Micro-Tech Hearing Instruments Certificate Renewal

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
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Date	Reference Number	Action
06 January 2011	7624683	<p>Omni removed from the "issued to" address and audioSync added.</p> <p>Changes to subcontractor list: change of addresses for Starkey Mexico, Intricon and Starkey Laboratories Australia PTY. The removal of Mimosa Acoustics and Audiotecnica di Lo Coco.</p> <p>The removal of final manufacture from service supplied by Starkey Laboratories, Poland and Starkey Laboratories (Germany) GmbH.</p> <p>The addition of Altron, Inc, IntriCon Pte Ltd and OEM Worldwide and Starkey (Suzhou) Hearing Technology Co., Ltd as significant subcontractors for manufacture.</p> <p>OEM subcontractor name changed to OEM Worldwide.</p>

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Date	Reference Number	Action
19 December 2011	7650459	Certificate renewal. Binaural equalizers and otoacoustic emission measurement systems removed from scope. The following changes were made to the list of significant subcontractors: EU representative activity added to Hazel grove location; Starkey Sweden removed; minor amendment to Arlington Labs address; Starkey Hungary removed; minor amendment to Starkey Mexico address; Intricon address updated; Starkey Germany removed.
30 November 2016	8573505	Certificate Renewal Removal of Arlington Lab, Strakey-Canada, Poland, Australia, Micro-Tech hearing, Altron inc, OEM in the subcontractor list Change of legal manufacturer address details to 'Starkey Laboratories, Inc., doing business as Starkey Hearing Technologies, under the brand names Starkey, Paradigm, Audibel, AudioSync, Audika, VISAUDIO, ProAkustik, Silvertone, NuEar and MicroTech, 6600 Washington Avenue South, Eden Prairie, Minnesota, 55344, USA' Removal of audiometers from certificate scope

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