

# Certificate

## Full Quality Assurance

No. CE 01505



Issued to:

**Starkey Laboratories, Inc**  
also trading as **Paradigm Hybrid**  
**Microelectronics, Audibel,**  
**AudioSync, Qualitone,**  
**NuEar and Micro-Tech**  
**6700 Washington Avenue 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; and audiometers**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

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

A handwritten signature in black ink that reads "Rob Wallis".

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Rob Wallis, Chair Certification Body Management Committee

First Issued: 23 Dec 1996

Date: 19 Dec 2011

Expiration Date: 22 Dec 2016

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*Conditions of Approval*

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

*raising standards worldwide*<sup>TM</sup>





# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Starkey Laboratories, Inc  
6600 Washington Avenue South  
Eden Prairie  
Minnesota  
55344  
USA

Holds Certificate No: FM 91716

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

The design, manufacture and service of analog, programmable, and digital custom in-the-ear and behind-the-ear hearing aids, hearing aid programming systems, binaural equalizers, and audiometers. Development and manufacture of hybrid circuitry designated for final use in hearing aid devices.

The scope of registration includes activities at: 2915 10th Street East, Glencoe, Minnesota 55336

For and on behalf of BSI:

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VP Regulatory Affairs, BSI Group America Inc.

Originally Registered: 07/01/2004

Latest Issue: 12/17/2012

Expiry Date: 12/07/2015



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...making excellence a habit.<sup>TM</sup>

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.  
A Member of the BSI Group of Companies.

Certificate No: FM 91716

Location

Registered Activities

Starkey Laboratories, Inc 6600 Washington Avenue South Eden Prairie Minnesota 55344 USA	The design, manufacture and service of analog and digital custom in-the-ear and behind-the-ear hearing aids, hearing aid programming systems and audiometers. Development of hybrid circuitry designated for final use in hearing aid devices.
Starkey de Mexico S.A de CV Calle Norte 7 Lote 2 y 3 Entre Diagonal Lorenzo de la Garza Y Poniente 2 Colonia Ciudad Industrial H. Matamoros Tamaulipas CP 87499 Mexico	The manufacture and service of analog and digital custom in-the-ear and behind-the-ear hearing aid products.
Starkey Laboratories Poland sp.z.o.o. ul. Wirazowa 119 Warsaw 02-145 Poland	The manufacture and service of analog and digital custom in-the-ear and behind-the-ear hearing aid products, including custom ear moulds.
Starkey (Suzhou) Hearing Technology Co., Ltd. C2 Block 128 Hongye Road SIP Suzhou Jiangsu 215006 China	The manufacture and service of analog and digital custom in-the-ear and behind-the-ear hearing aid products. The manufacture of hybrid circuitry designated for final use in hearing aid devices.
Starkey Labs Canada Co. 7310 Rapistan Court Mississauga Ontario L5N 6L8 Canada	The manufacture and service of custom and standard hearing aid products, including ear molds from Starkey Laboratories Canada Limited.  Starkey BTE Aids, Starkey Custom Aids, Starkey Audiometers, Starkey Hearing Test Systems, Starkey Diagnostic Systems.

This appendix supersedes Certificate FM 72336 originally issued 20 December 2002.

Originally Registered: 07/01/2004

Latest Issue: 12/17/2012

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Location

Registered Activities

Starkey France S.A.R.L. 23 Rue Claude Nicolas Ledoux Europarc Batiment 14 Creteil 94000 France	Manufacturing, marketing, sales and servicing (after sales support, training) of hearing aids and pre-wired plate. Sales of hearing aid accessories, manufacturing, marketing and sales of ear moulds.
Starkey Laboratories Australia PTY 75-85 O'Riordan Street South Sydney Corporate Park Alexandria New South Wales 2015 Australia	The manufacture, sale and service of custom hearing aids, including ear moulds. The sale and service of standard hearing aids.
Starkey Laboratories Limited William F. Austin House Bramhall Technology Park Hazel Grove Stockport Cheshire SK7 5BX United Kingdom	The manufacture and service of analog and digital custom in-the-ear and behind-the-ear hearing aid products, including custom ear moulds.
Starkey Italy S.r.l. via Torino, 51 20063 Cernusco Sul Naviglio Milano (MI) Italy	The manufacture and service of analog and digital custom in-the-ear and behind-the-ear hearing aid products, including custom ear moulds.

Originally Registered: 07/01/2004

Latest Issue: 12/17/2012

Expiry Date: 12/07/2015

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