

# EC Certificate - Full Quality Assurance System

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

**No.** CE 594667  
**Issued To:** **Jacoti bvba**  
**Vlamingstraat 4**  
**Wevelgem**  
**8560**  
**Belgium**

In respect of:

**The design and manufacture of software applications for hearing impaired users and hearing experts**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2016-02-10**

Date: **2019-01-10**

Expiry Date: **2023-08-05**

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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**

Jacoti Hearing Technologies S.L.  
Via Augusta 158, 8-2  
Barcelona  
08006  
Spain

**Design**  
**Manufacture**

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## Certificate History

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Date	Reference Number	Action
10 February 2016	8465915	First issue, transfer from another Notified Body.
17 March 2016	8499020	Reissue due to change in address of subcontractor, Jacoti Hearing Technologies S.L. from 'Diagonal 349, 1-1, Barcelona 08037' to 'Via Augusta 158, 8-2, Barcelona 08006'.
17 July 2018	8923271	Certificate Renewal.
Current	8855749	Traceable to NB 0086.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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