

# EC Certificate - Production Quality Assurance

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

**No.**

**CE 668686**

Issued To:

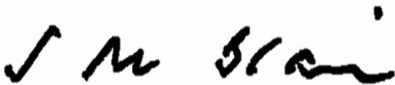
**eMoyoDotNet (Pty) Ltd  
1st Floor, Silhouette Building  
179 Beyers Naude Drive  
Northcliff  
Johannesburg  
South Africa**

In respect of:

**Manufacture of portable audiometers**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2017-05-11**

Date: **2017-05-11**

Expiry Date: **2022-05-10**

...making excellence a habit.™

Page 1 of 1

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.

# EC Certificate - Production Quality Assurance

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

## List of Significant Subcontractors

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

Certificate No: **CE 668686**  
Date: **2017-05-11**  
Issued To: **eMoyoDotNet (Pty) Ltd**  
**1st Floor, Silhouette Building**  
**179 Beyers Naude Drive**  
**Northcliff**  
**Johannesburg**  
**South Africa**

**Subcontractor:**

**Service(s) supplied**

PSF Medical BV  
Marten Meesweg 8  
3068 AV Rotterdam  
The Netherlands

**EU Representative**

...making excellence a habit.™

# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 668686**  
Date: **2017-05-11**  
Issued To: **eMoyoDotNet (Pty) Ltd  
1st Floor, Silhouette Building  
179 Beyers Naude Drive  
Northcliff  
Johannesburg  
South Africa**

Date	Reference Number	Action
11 May 2017	8682025	Initial Issue

...making excellence a habit.™

Page 1 of 1

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.