

# EC Certificate - Production Quality Assurance

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

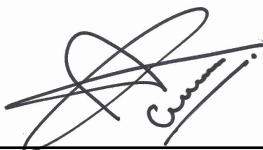
**No.** CE 698848  
**Issued To:** SiSU Wellness Pty Ltd  
442 Auburn Road  
Hawthorn  
Victoria  
3122  
Australia

In respect of:

**Manufacture of Medical Device Stations to provide Biometric Measurements, such as Height, Weight, BMI, Blood Pressure, Body Composition, Heart Age and Risk of Diabetes.**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2019-03-21**

Date: **2019-03-26**

Expiry Date: **2024-03-20**

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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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## Supplementary Information to CE 698848

Issued To:

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**Victoria**  
**3122**  
**Australia**

Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD1301, MD1302, MDS 7010	Medical device stations to provide biometric measurements.	N/A

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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

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

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**442 Auburn Road**  
**Hawthorn**  
**Victoria**  
**3122**  
**Australia**

**Subcontractor:**

**Service(s) supplied**

SiSU Wellness Ltd  
35 Kingsland Road  
London  
E2 8AA  
UK

**EU Representative**

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# EC Certificate - Production Quality Assurance Certificate History

**Certificate No:** CE 698848  
**Date:** 2019-03-26  
**Issued To:** SiSU Wellness Pty Ltd  
 442 Auburn Road  
 Hawthorn  
 Victoria  
 3122  
 Australia

Date	Reference Number	Action
21 March 2019	9642440	First Issue.
Current	9700818	Traceable to NB 0086.

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