

# EC Certificate - Full Quality Assurance System

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

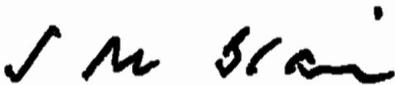
**No.** **CE 688840**  
**Issued To:** **Bio-Beat Technologies Ltd**  
**HaMagshimim St. 26,Suite 202**  
**Petach Tikva**  
**4934835**  
**Israel**

In respect of:

**Design and manufacture of wearable devices for the measurement, spot-checking monitoring, displaying and storage of physiological parameters (blood oxygen saturation, pulse rate, non-invasive blood pressure, cardiac output and stroke volume) as an adjunct in the assessment of cardiovascular and respiratory status of adult patients.**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2019-03-19**

Date: **2019-03-19**

Expiry Date: **2024-03-18**

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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.

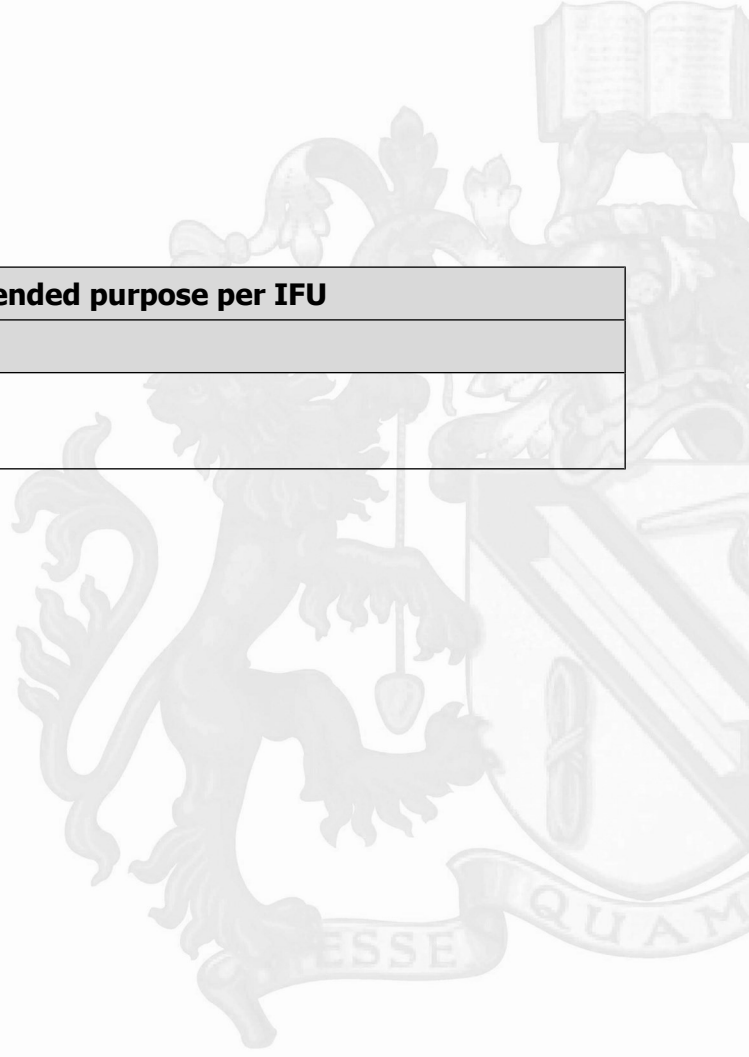
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## Supplementary Information to CE 688840

Issued To:

**Bio-Beat Technologies Ltd**  
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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD1302 MDS7010	Monitoring device of vital physiological parameters.	N/A



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## List of Significant Subcontractors

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

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**Israel**

**Subcontractor:**

**Service(s) supplied**

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Nistec Ltd.  
HaSivim St. 43  
Petach Tikva  
4959501  
Israel

**Manufacture**

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Obelis s.a.  
Bd. Général Wahis 53  
Brussels  
1030  
Belgium

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 688840**  
Date: **2019-03-19**  
Issued To: **Bio-Beat Technologies Ltd**  
**HaMagshimim St. 26,Suite 202**  
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**Israel**

Date	Reference Number	Action
Current	8891805	Initial Release.

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