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 and associated software for the measurement, spot-checking monitoring, displaying and storage of physiological parameters (blood oxygen saturation, pulse rate, non-invasive blood pressure, cardiac output, stroke volume, respiratory rate, skin temperature, one lead EKG, mean arterial pressure, pulse pressure, systemic vascular resistance, cardiac index and pulse rate variability) 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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-03-19** Date: **2021-04-27** Expiry Date: **2024-03-18**

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Supplementary Information to CE 688840

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1302 MDS7010	Monitoring device of vital physiological parameters.	N/A
MD 1111	Software associated with monitoring devices of vital physiological parameters	N/A

First Issued: **2019-03-19** Date: **2021-04-27** Expiry Date: **2024-03-18**

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List of Significant Subcontractors

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

Certificate No:	**CE 688840**
Date:	**2021-04-27**
Issued To:	**Bio-Beat Technologies Ltd** **HaMagshimim St. 26,Suite 202** **Petach Tikva** **4934835** **Israel**

Subcontractor:	**Service(s) supplied**
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: **2021-04-27**

Issued To: **Bio-Beat Technologies Ltd**
HaMagshimim St. 26,Suite 202
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Date	Reference Number	Action
19 March 2019	8891805	Initial Release.
19 March 2019	8898168	Traceable to NB 0086.
Current	3257631	Supplemented – addition of device category MD 1111 to the device table and scope updated from "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." To "Design and manufacture of wearable devices and associated software for the measurement, spot-checking monitoring, displaying and storage of physiological parameters (blood oxygen saturation, pulse rate, non-invasive blood pressure, cardiac output, stroke volume, respiratory rate, skin temperature, one lead EKG, mean arterial pressure, pulse pressure, systemic vascular resistance, cardiac index and pulse rate variability) as an adjunct in the assessment of cardiovascular and respiratory status of adult patients." Removal of the subcontractor: Nistec Ltd., HaSivim St. 43, Petach Tikva, 4959501 Israel.