By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 631058**

Issued To: **BioSerenity**
ICM-iPEPS
47 Boulevard de l'Hôpital
Paris
75013
France

In respect of:

Design and manufacture of wearable devices and related software applications for the diagnosis and monitoring of electrophysiological, optical, actigraphic and wave signals.

Conception et fabrication de vêtements connectés et applications logicielles associées pour le diagnostic et le monitorage des signaux électrophysiologiques, optiques, actimétriques et ondes.

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: **2016-05-10** Date: **2020-09-04** Expiry Date: **2024-05-26**

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Supplementary Information to CE 631058

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NBOG codes(s)	Device Description	Intended purpose
Class IIa		
MD 1301 MD 1302 MD 1111 MDS 7010	Monitoring devices for non-critical care	N/A - for Class IIa devices

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List of Significant Subcontractors

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

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Date:	**2020-09-04**
Issued To:	**BioSerenity** **ICM-iPEPS** **47 Boulevard de l'Hôpital** **Paris** **75013** **France**

Subcontractor:	**Service(s) supplied**
BioSerenity 12 rue Gustave Eiffel Rosières près de Troyes 10430 France	**Manufacture**
BioSerenity 20 Rue Berbier du Mets Paris 75013 France	**Control of Manufacture** **Design**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 631058**

Date: **2020-09-04**

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Date	Reference Number	Action
10 May 2016	8285436	First issue.
12 February 2018	8868340	Change of address for BioSerenity manufacturing site from 270 rue du Faubourg Croncels, 10 000 Troyes, France to 12 rue Gustave Eiffel, 10 430 Rosières près de Troyes, France.
12 March 2019	9669630	Addition of location "BioSerenity, 20 Rue Berbier du Mets, Paris, 75013, France". Addition of devices table.
13 March 2019	8760336	Traceable to NB 0086.
18 March 2020	3124368	Change of address from 47-85 Boulevard de l'Hôpital to 47 Boulevard de l'Hôpital
Current	3252385	Renewal