

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BioSerenity Medical Devices Group
20 rue Berbier du MetS
Paris
75013
France

Facility ID Number: F006936

Holds Certificate No:

MDSAP 802594

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, Manufacture, Servicing and Distribution of Wearable Devices and Related Software Applications for the Diagnosis and Monitoring of Electrophysiological, Optical, Actigraphic and Wave Signals.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-06-04

Effective Date: 2024-06-04

Expiry Date: 2027-06-03



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 802594**

Location

Registered Activities

BioSerenity Medical Devices Group
20 rue Berbier du Mets
Paris
75013
France
Facility ID Number: F006936

Design, Manufacture, Servicing and Distribution of Wearable Devices and Related Software Applications for the Diagnosis and Monitoring of Electrophysiological, Optical, Actigraphic and Wave Signals.

BioSerenity Medical Devices Group
12 rue Gustave Eiffel
Rosières près de Troyes
10430
France
Facility ID Number: F006937

Manufacture, Servicing and Distribution of Wearable Devices and Related Software Applications for the Diagnosis and Monitoring of Electrophysiological, Optical, Actigraphic and Wave Signals.



Original Registration Date: 2024-06-04

Effective Date: 2024-06-04

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.