ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 003177 0002 Rev. 02

Certificate Holder: **BioSerenity SAS**
47 Boulevard de l´Hopital
75013 Paris
FRANCE

Certification Mark:

Scope of Certificate: **Design, Manufacture, Servicing, and Distribution of Wearable Devices and related Software Applications for the Diagnosis and Monitoring of Electrophysiological, Optical, Actigraphic and Wave Signals**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001191**

Effective Date: **2021-09-15**

Expiry Date: **2024-06-18**

Date of Issue: 2021-10-07

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: **Audit/Certification Criteria**

Canada
- Medical Device Regulations – Part 1- SOR 98/282

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

BioSerenity SAS
47 Boulevard de l´Hopital, 75013 Paris, FRANCE

BioSerenity SAS
12 Rue Gustave Eiffel, 10430 Rosieres Pres Troyes, FRANCE

Bioserenity SAS
20 rue Berbier du Mets, 75013 Paris, FRANCE

Facility Scopes:

BioSerenity SAS
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Design, Manufacture, Servicing, and Distribution of Wearable Devices and related Software Applications for the Diagnosis and Monitoring of Electrophysiological, Optical, Actigraphic and Wave Signals
REPs Facility ID: F001191

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REPs Facility ID: F002098

Date of Issue: 2021-10-07

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No. QS6 003177 0002 Rev. 02

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Design and Distribution of Wearable Devices and related Software Applications for the Diagnosis and Monitoring of Electrophysiological, Optical, Actigraphic and Wave Signals
REPs Facility ID: F00119

Date of Issue: 2021-10-07

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