



America

# CERTIFICATE

No. QS6 18 06 03177 001

**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:** Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA.  
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

<http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**DUNS No:** 26-582-8238  
**Effective Date:** 2018-06-19  
**Expiry Date:** 2021-06-18

Manuel Bradaric  
MHS Certification Manager



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

**BioSerenity SAS**  
12 Rue Gustave Eiffel  
10430 Rosieres Pres Troyes  
FRANCE  
DUNS No: 26-992-2554

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

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## Audit/Certification Criteria

### Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

### Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

### Canada

- Medical Device Regulations SOR/98-282, Part 1

### United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

### Japan

- MHLW Ministerial Ordinance No.169, 2004

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