bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BioSerenity Medical Devices Group
6/8 Rue Jean Antoine de Baïf
Paris
75013
France

Facility ID Number: F006936
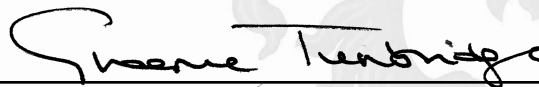
Holds Certificate No: **MDSAP 802594**

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 EEG recorders and related software with single use and reusable electrode caps for the area of neurology.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-06-04   Effective Date: 2025-08-13   Expiry Date: 2027-06-03

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 802594**

Location	Registered Activities
BioSerenity Medical Devices Group 6/8 Rue Jean Antoine de Baïf Paris 75013 France Facility ID Number: F006936	Design, manufacture, servicing and distribution of EEG recorders and related software with single use and reusable electrode caps for the area of neurology.
BioSerenity Medical Devices Group 12 rue Gustave Eiffel Rosières près de Troyes 10430 France Facility ID Number: F006937	Manufacture, servicing and distribution of EEG recorders and related software with single use and reusable electrode caps for the area of neurology.

Original Registration Date: 2024-06-04   Effective Date: 2025-08-13   Expiry Date: 2027-06-03