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CERTIFICATE
OF REGISTRATION

This is to certify that the management system of:

EnsoData, Inc.

(FIN F004427)

Main Site: 10 E Doty St., Suite 449,

Madison, Wisconsin, 53703, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design and development, manufacture, installation and service of medical software intended to analyze physiological signals and aid in the diagnosis of sleep, neurological, respiratory, and cardiac disorders.

Certificate Number:
0114218

Revision Level: 04

Initial Certification Date:
2021-06-09

Certification Effective Date:
2025-09-16

Certification Expiry Date:
2027-06-08

ISO 13485:2016 CERTIFICATION ™

MDSAP
Medical Device Single Audit Program

intertek

Rathin Grover
President, Business Assurance

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