Certificate

Certificate No.:	MD 1323729-1-1
Manufacturer:	**Cordiana Medical Informatics AG** Platz 4 6039 Root D4 Switzerland
REPs Facility ID:	F007590
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure 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
Scope:	Design and development, manufacturing, distribution, installation and service of software for analysis of cardiopulmonary records for diagnosis

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	1160263-230
Issue Date:	2024-09-26
Effective Date:	2024-09-26
Expiry Date:	2027-09-25

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

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