

Certificate

Certificate No.: MD 84953130-190

Manufacturer: **MEDICALGORITHMICS S.A.**
Al. Jerozolimskie 81
02-001 Warszawa
Poland

REPs Facility ID: F001083

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, manufacture, distribution and servicing
of ECG holter systems and cardiac rehabilitation monitoring
systems, containing ECG signal recorders and software for viewing
and analysis of ECG signals.

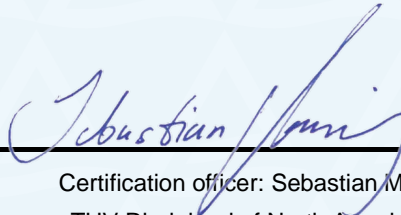
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject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

Project No.: 84953130 - 60, 70

Issue Date: 2021-11-10

Effective Date: 2021-11-10

Expiry Date: 2024-08-17



Certification officer: Sebastian Mniszek
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9108648035?locale=en
or calling 1-888-743-4652.

Certificate

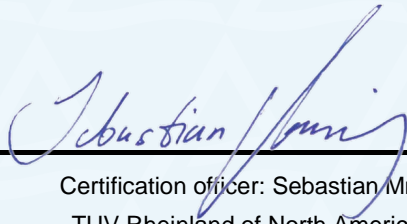
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The scope of certification includes the following additional sites:

No.	Location	Scope
/01	MEDICALGORITHMICS S.A. Al. Jerozolimskie 81 02-001 Warszawa Poland	Design and development, manufacture, distribution and servicing of ECG holter systems and cardiac rehabilitation monitoring systems, containing ECG signal recorders and software for viewing and analysis of ECG signals. REPs Facility ID: F001083
/02	MEDICALGORITHMICS S.A. ul. Marynarki Polskiej 100 80-557 Gdańsk Poland	Design and development, manufacture, distribution and servicing of ECG holter systems and cardiac rehabilitation monitoring systems, containing ECG signal recorders. REPs Facility ID: F002010

TÜV Rheinland

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