

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2072796-1

Organization: Leadtek Research Inc.
18F, No.166, Jian-Yi Rd., Chung Ho Dist.,
New Taipei City 23511
Taiwan

Scope: Design and Development, Manufacture and Distribution of
Electrocardiograph (ECG) and Heart Rate Variability (HRV) Analyzers,
Pulse Oximeters and phonocardiograph recorders;
Contract Manufacture of Wireless Monitoring and Connective Electronic
Devices for Medical Use;
Contract Manufacture of Electrocardiograph and phonocardiograph
recorders.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 238515986-040
Effective date: 2021-12-13
Expiry date: 2024-12-12
Issue date: 2021-11-30



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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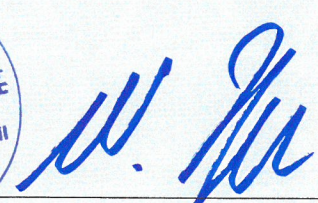
Organization: Leadtek Research Inc.
18F, No.166, Jian-Yi Rd., Chung Ho Dist.,
New Taipei City 23511
Taiwan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Leadtek Research Inc. 18F, No.166, Jian-Yi Rd., Chung Ho Dist., New Taipei City 23511 Taiwan	Design and Development, Distribution of Electrocardiograph (ECG) and Heart Rate Variability (HRV) Analyzers, Pulse Oximeters and phonocardiograph recorders; Contract Manufacture of Wireless Monitoring and Connective Electronic Devices for Medical Use; Contract Manufacture of Electrocardiograph and phonocardiograph recorders.
/02	c/o Leadtek Research Inc. 5F, No. 2, Alley 11, Lane 327, Sec. 2, Chung San Rd., Chung Ho Dist., New Taipei City, 23585 Taiwan	Manufacture of Electrocardiograph (ECG) and Heart Rate Variability (HRV) Analyzers, Pulse Oximeters and phonocardiograph recorders; Contract Manufacture of Wireless Monitoring and Connective Electronic Devices for Medical Use; Contract Manufacture of Electrocardiograph and phonocardiograph recorders.

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Taiwan

The scope of certification also covers the following:

/03 c/o Leadtek Research Inc.
2F, No. 4, Alley 11, Lane 327, sec. 2,
Chung San Rd., Chung Ho Dist.,
New Taipei City, 23585
Taiwan

Manufacture of Electrocardiograph (ECG)
and Heart Rate Variability (HRV) Analyzers,
Pulse Oximeters and phonocardiograph
recorders;
Contract Manufacture of Electrocardiograph
and phonocardiograph recorders.

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