Test Report issued under the responsibility of:

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	N40P0001
Date of issue ..... :	Mar 23, 2020
Total number of pages ..... :	145
CB Testing Laboratory ..... :	SGS Germany GmbH, CRS Munich
Address ..... :	Hofmannstrasse 50, 81379 Munich, Germany
Applicant's name ..... :	**ADLINK Technology GmbH**
Address ..... :	Ulrichsberger Str. 17 94469 Deggendorf, Germany
Test specification:	
Standard..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure ..... :	CB Scheme
Non-standard test method..... :	N/A
Test Report Form No. ..... :	IEC60601_1K
Test Report Form(s) Originator . :	UL(US)
Master TRF ..... :	2015-11

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Digitally signed by Abramov Ivan
Date: 2022.08.22 08:28:10 EEST
Reason: MoldSign Signature
Location: Moldova

Test item description .....:	Medical Panel Computer
Trade Mark ..... :	ADLINK Leading EDGE COMPUTING
Manufacturer ..... :	ADLINK Technology GmbH
Model/Type reference ..... :	MLC 8 series (MLC8-21, MLC8-23, MLC8-27)
Ratings ..... :	100 – 240 Vac; 1,5 A – 0,75 A; 50/60 Hz

Testing procedure and testing location:			
☒	**CB Testing Laboratory:**	SGS Germany GmbH, CRS Munich	
Testing location/ address..... :		Hofmannstrasse 50, 81379 Munich, Germany	
Tested by (name, function, signature) ..... :		Stefan Koschke Qualification Engineer	Stefan Koschke
Approved by (name, function, signature)..... :		Katja Blaesing Qualification Engineer	Blaesing
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature)..... :			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) ..... :			
Approved by (name, function, signature)..... :			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) ..... :			
Approved by (name, function, signature)..... :			
Supervised by (name, function, signature) ..... :			

List of Attachments:

- IEC 60601-1-6 Test Report No.: N40P0002 of SGS Germany GmbH (kept in file)
- IEC 60601-1-2 Test Report No.: N40P0010 of SGS Germany GmbH (kept in file)
- IEC 60601-1-2 Test Report No.: N40P0014 of SGS Germany GmbH (kept in file)

Summary of testing:

Tests performed (name of test and test clause):

Clause	Tests
4.11	Power Input
5.7	Humidity Preconditioning treatment
7.1.2	Legibility of markings
7.1.3	Durability of Marking Test
8.4.3	ME equipment intended to be connected to a power source by a plug
8.6.4	Impedance and current-carrying capability of protective earth connections
8.7	Leakage currents and Patient auxiliary currents
8.7.4.7	Patient Leakage Current – measurements made under special test conditions
8.8.3	Dielectric Strength
8.9.4	Measurement of Creepage Distances and Air Clearances
11.1	Maximum temperature during normal use
11.6.3	Spillage test
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS
11.8	Interruption of the power supply / supply mains to ME equipment
13.2	Single fault conditions
15.3.2	Push test
15.3.3	Impact test
15.3.4	Drop test

Testing location:

SGS Germany GmbH, CRS Munich
Hofmannstrasse 50
81379 Munich
Germany

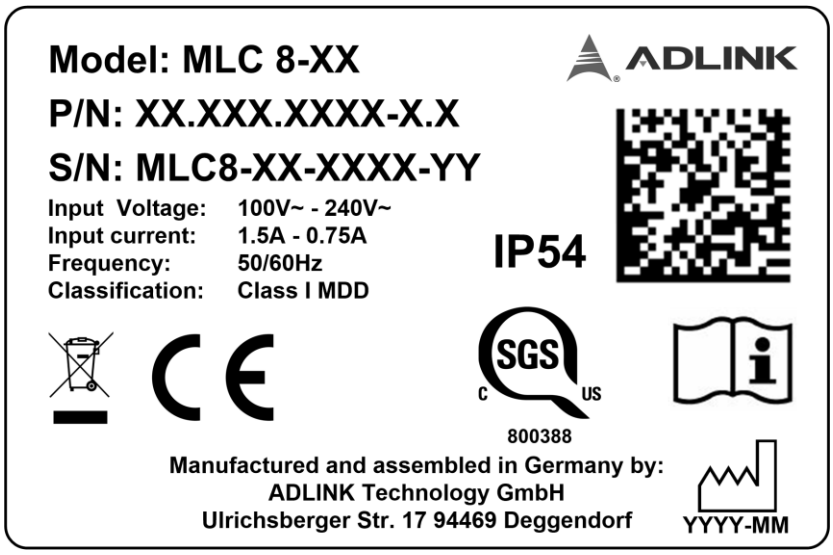
Summary of compliance with National Differences

☒ National Differences CA, US, CH, JP, KR

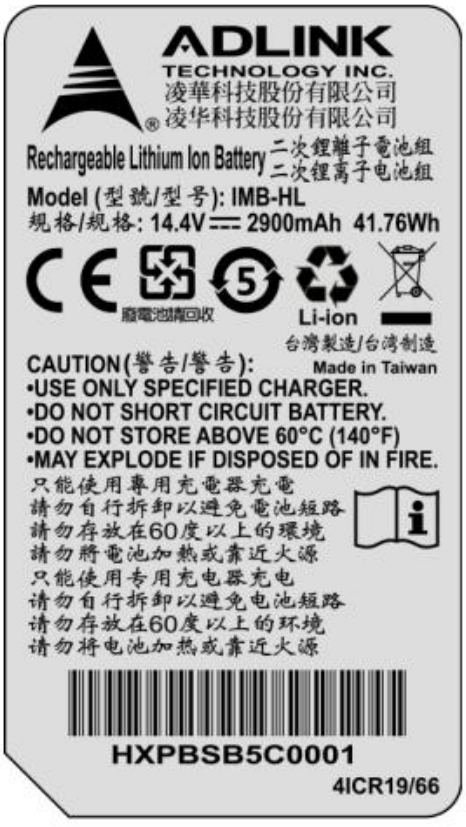
Explanation of Codes:
CA=Canada, CH=Switzerland, JP=Japan, KR=Korea, US=United States of America

Copy of marking plate

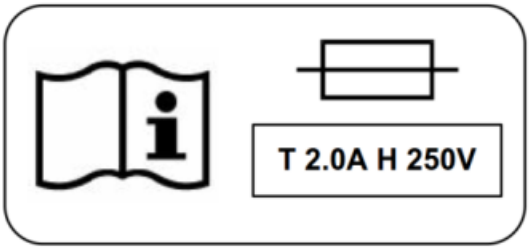
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Product identification label



Battery pack label



Mains input fuse label

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Stationary
Device type (component/sub-assembly/ equipment/ system) :	Equipment
Intended use (Including type of patient, application location) :	The All-in-One panel computers of the MLC 8 series are devices compliant to medical purpose and are intended to display, monitor and store data accumulating while processing medical and / or patient data in medical environments
Mode of operation ..... :	Continuous
Supply connection	Appliance coupler
Accessories and detachable parts included ..... :	None
Other options include ..... :	--
Testing ..... :	
Date of receipt of test item ..... :	Jul 08, 2019
Date(s) of performance of tests ..... :	Jul 08, 2019 to Nov 06, 2019
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	Pass (P)
- test object was not evaluated for the requirement ..... :	N/E (collateral standards only)
- test object does not meet the requirement ..... :	Fail (F)
Abbreviations used in the report:	
- normal condition ..... : N.C.	- single fault condition ..... : S.F.C.
- means of Operator protection ..... : MOOP	- means of Patient protection ..... : MOPP

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided.....:	☐ Yes ☒ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) .....:	**Same as applicant**

General product information:

The product is an all-in-one medical panel computer system intended for use in medical environment (hospitals, medical centers, physician's facilities etc.).

It is and are intended to display, monitor and store data accumulating while processing medical and / or patient data in medical environments such as surgical OR theatres, intensive care units, emergency care units and further point-of-care sites in health care facilities like hospitals, out-patient care units and other medical care units.

The device provides medically relevant information to medical personnel. Patient and / or surgical and medical data are displayed, processed and stored locally or can be exported to external systems. The device is intended to be operated within the scope of the intended purpose by medical personnel working in health care facilities. Furthermore persons functioning as device administrators are intended to use the device and to maintain the device to the extent described in the according device manual.

The device is neither intended to be operated by, nor intended to be connected directly to patients (unless used as part of a medical system, configured by a third party).

The product is a Medical PC intended for stand-alone use or for usage in conjunction with (other) medical electrical equipment.

A dedicated type of patient is not specified and is depending on end medical use. The device is used inside patient environment, patients may come unintended in contact with parts of the device.

The maximum operating ambient temperature is +30 °C.

The device does not offer any essential performance itself. Essential performance depends on end user application.

The average service life-time of the device used within the limits of the intended purpose ranges from 3 to in max. 7 years.

The device is not intended to be used near high intensity emission equipment such as HF surgery devices or magnetic resonance imaging equipment in oxygen rich or flammable anesthetic environments

The device incorporates the LCD panel and computational elements in one enclosure. All operating controls are located on the lower front side. All connectors (I/O interfaces) are provided at the back-bottom side, underneath the cable cover. Depending from the product variation, the device is available with or without PCAP (projected capacitive) touch screen functionality.

Manufacturer and applicant of the product is ADLINK Technology GmbH, referenced as ATG. Trademark of the computer is provided on the device marking label.

The MLC 8 series devices can be identified via the assembled LCD panel size and power input. Sub variants are generated via different CPUs, optional interfaces and extensions such as WLAN/Bluetooth modules or various storage medium capacities. Sub variants are not reflected by key codes but tracked via serial number and device database entries.

All variants are available with incorporated PSU connected to mains

Tested Configuration:

Component	Type	Identification No	Iss.	Serial No	Comment
Medical Panel Computer	MLC 8-21	--	--	MLC8-21-0001-19	--
Medical Panel Computer	MLC 8-23	--	--	MLC8-23-0001-19	--
Medical Panel Computer	MLC 8-27	--	--	MLC8-27-0001-19	--

Conditions of Acceptability:

1. The system is to be installed, switched on and maintained only by suitably trained and qualified personnel in accordance with the installation instructions provided with the EUT.
2. The maximal acceptable operating temperature is +30 °C
3. The EUT is reliable connected to ground. For testing of clause 8.6.4 a detachable cord with 2 m length has been used (refer to table 8.10), different length shall be considered in end use application
4. Manual checked in English; for placing the product on other markets it should be in local language.
5. The device does not offer any essential performance itself. Essential performance must be evaluated in final end user application.
6. Any mechanical provisions to mount the displays are not part of this investigation and shall be considered in final end user application
7. All connected IT equipment must comply with appropriate standards and shall be considered in end use application
8. Performance of installed software and connection to an IT network (Chapter 14 of this standard) shall be considered in end use application

Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1-2
Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Report Number. ..... :	**N40P0014**
Date of issue ..... :	**Feb 24, 2020**
Total number of pages ..... :	**85**
Name of Testing Laboratory preparing the Report ..... :	**SGS Germany GmbH, Consumer and Retail Hofmannstrasse 50 81379 Munich, Germany**
Applicant's name ..... :	**ADLINK Technology GmbH**
Address ..... :	**Ulrichsberger Str. 17 94469 Deggendorf Germany**
Test specification:	
Standard ..... :	IEC 60601-1-2:2014
Test procedure ..... :	CB
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1_2E_EMC
Test Report Form(s) Originator .... :	UL(US)
Master TRF ..... :	2017-03

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

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General disclaimer:

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Test item description	**Medical Panel Computer**
Trade Mark	ADLINK Leading EDGE COMPUTING
Manufacturer	**ADLINK Technology GmbH**
Model/Type reference	**MLC 8 series:** **- MLC8-23**
Ratings	**100 – 240 V ac; 50/60 Hz; Class 1**

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**CB Testing Laboratory:**	**SGS Germany GmbH, Consumer and Retail**	
Testing location/ address		**Hofmannstrasse 50** **81379 Munich, Germany**	
Tested by (name, function, signature)			Sperling
Approved by (name, function, signature)			Wössner
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address			
Tested by (name, function, signature)			
Approved by (name, function, signature)			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address			
Tested by (name, function, signature)			
Witnessed by (name, function, signature)			
Approved by (name, function, signature)			

☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....			
Tested by (name, function, signature).....			
Witnessed by (name, function, signature).....			
Approved by (name, function, signature).....			
Supervised by (name, function, signature).....			

List of Attachments (including a total number of pages in each attachment):
None

Summary of testing:

Tests performed (name of test and subclause):	**Testing location:**
Conducted EMISSIONS (7.3)	**SGS Germany**
Radiated EMISSIONS (7.3)	**Consumer and Retail, EMC-Lab**
Disturbance Power EMISSIONS (7.3)	**81379 Munich, Germany**
Harmonic Currents (7.2.1)	
Voltage Fluctuations and Flicker (7.2.3)	
Electrostatic Discharges (8.9)	
RF Electromagnetic Fields (8.9)	
Proximity fields from RF wireless communications EQUIPMENT (8.10)	
Electrical Fast Transients (8.9)	
Surge (8.9)	
Conducted Disturbances Induced by RF Fields (8.9)	
Voltage Dips and Interruptions (8.9)	

Note: delete tests not conducted in the list above.

Summary of compliance with National Differences:
List of countries addressed
.....

☒ **The product fulfils the requirements of IEC 60601-1-2: 2014 (Fourth Edition)**