ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

C E R T I F I C A T E

No. U8 109019 0004 Rev. 00

Holder of Certificate: **MACTRON GROUP CO., LTD**
2F., No.86, Xinhu 1st Road
Neihu District
11494 Taipei
TAIWAN

Certification Mark:

Product: **Other IT and business equipment**
(Medical Premium Windows Touch Panel PC)

This product was voluntarily tested to the relevant safety requirements referenced on this certificate. It can be marked with the certification mark above. The mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing and Certification Regulations". TÜV SÜD America Inc. is an OSHA recognized NRTL for USA and a Standards Council of Canada ISO/IEC 17065 accredited Certification body for Canada.

Test report no.: 081-220236-000

Date, 2022-05-27

(Watson Yang)

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA

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C E R T I F I C A T E

No. U8 109019 0004 Rev. 00

Model(s):	**WCP2157, WMP2157**
Brand Name:	**MACTRON GROUP**
Brand:	MACTRON GROUP
Tested according to:	ANSI/AAMI ES60601-1:2005/R:2012-08 CAN/CSA C22.2 No. 60601-1:2014-03

Parameters:

Rated input voltage:	19 Vdc
Rated input current:	4.74 A
Protection class:	Class I equipment, no applied part
Degree of protection against ingress of liquids:	IPX0

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C E R T I F I C A T E

No. U8 109019 0004 Rev. 00

License Conditions:

1. The product is a Medical Premium Windows Touch Panel PC which regarded as Medical Device Data Systems (MDDS).
   It is a hardware product that transfer, store, convert formats, and display medical device data. These products do not modify the data or modify the display of the data, and it does not by itself control the functions or parameters of any other medical device. It is not intended for use in conjunction with medicines or other medical technologies.

2. The EUT power supplied by certified Class I External Power Adapter (FSP Group Inc / FSP090-RBBM1)
   The rating of Supplied by External Power Adapter:
   Input: 100-240 Vac, 47-63 Hz, 1.5-0.6 A
   Output: 19 Vdc, 4.74 A

3. The maximum specified ambient temperature is 40 ºC.

4. The equipment is evaluated for operating in altitude up to 5,000 m.

5. The equipment provides Means of Patient Protection (MOPP).

6. The following clauses were not part of the manufacturers order and therefore excluded from this testing:
   11.7: Biocompatibility of ME EQUIPMENT and ME SYSTEMS
   17: Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

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